UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

IN RE LEXICON PHARMACEUTICALS INC. SECURITIES LITIGATION	Case No. 4:19-CV-00301
THIS DOCUMENT RELATES TO: ALL ACTIONS	**JURY TRIAL DEMANDED**

FIRST AMENDED CLASS ACTION COMPLAINT

Lead Plaintiffs Paul E. Callinan and Jorge Rivera ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, for their complaint against defendants ("Defendants"), allege the following based upon personal knowledge as to themselves and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Lexicon Pharmaceuticals, Inc. ("Lexicon" or the "Company"), analysts' reports and advisories about Lexicon, interviews with former employees of Defendants, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

Counsel for Plaintiffs has conducted extensive due diligence in preparation of this First Amended Class Action Complaint ("Complaint"). Plaintiffs, among other things, retained the services of an independent investigation firm with extensive investigative experience, which made significant efforts to identify, locate, contact and interview former employees of Defendants with potentially relevant information to the allegations in this Complaint. Certain former employees are

quoted in this Complaint as confidential witnesses ("CWs"). All confidential witnesses are referred to in the masculine to protect their identities.

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Lexicon securities between March 11, 2016 and July 29, 2019, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Lexicon is a biopharmaceutical company founded in 1995 and headquartered in The Woodlands, Texas. Lexicon focuses on the development and commercialization of "breakthrough treatments," *i.e.*, drugs, "for the treatment of human diseases."

3. One of Lexicon's drugs is "sotagliflozin" (trademarked "Zynquista"), an oral drug candidate for treatment of type 1 diabetes ("T1d") and type 2 diabetes ("T2d"). Throughout the Class Period, Lexicon emphasized that sotagliflozin was one of its "most advanced drug programs" and that the Company was "devoting most of [its] resources to the commercialization or development" of its most advanced programs.

4. Lexicon claimed that, when used in conjunction with insulin, sotagliflozin can help people with T1d or T2d control their blood glucose levels by inhibiting their bodies' absorption or reabsorption of glucose in the gastrointestinal tract and/or kidneys. According to Lexicon, sotagliflozin prevents glucose absorption and reabsorption, and the non-absorbed glucose is passed out of the body through urination, reducing a diabetic's blood glucose level.

5. Lexicon was in poor financial condition throughout the Class Period. At the start of the Class Period, for example, Lexicon disclosed that it had ***$1.1 billion*** in debt compared with

revenues of only ***$130 million***. This spread between the Lexicon's debt and income widened considerably during the Class Period. As of December 31, 2018, the Company reported over ***$1.47 billion*** in debt compared with only ***$63.2 million*** in revenues. In addition, Lexicon's cash reserves ***plummeted 70%*** during the Class Period, from $521 million to ***only $162 million***.

6. FDA approval of sotagliflozin was thus central Lexicon's survival, let alone profitability. If approved, sotagliflozin would give Lexicon access to the enormous T1d treatment market, which pharmaceutical industry analysts estimated would reach ***$25.52 billion*** by 2024. Defendants also touted the market Lexicon would tap with sotagliflozin. For example, at a September 2018 healthcare conference sponsored by Wells Fargo, Defendant Coats told attendees that "We believe overall, the addressable market in type 1 is somewhere in the neighborhood of ***$5 billion***." Finally, a Jefferies analyst had predicted that, if approved, sotagliflozin's sales as a treatment for T1d could reach ***$1 billion annually***.

7. Defendants had learned from phase 2[1] clinical trials that there was a dramatically increased incidence of diabetic ketoacidosis ("DKA") in patients taking sotagliflozin. One of the most serious health risks for people with diabetes, DKA is a life-threatening condition that develops when people with diabetes do not produce enough insulin and thus cannot use the glucose

[1] "Clinical trials" are studies of a potential treatment for a disease or condition, which are performed on people. *See* FDA, *Step 3: Clinical Research*, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited July 30, 2019). There are four phases of clinical trials: Phase 1 trials test safety and dosage of a potential drug, last for several months and are performed on 20 to 100 volunteers; phase 2 trials test efficacy and side effects, last from several months to up to two years, and are performed on up to several hundred volunteers; phase 3 trials test efficacy and monitor for adverse reactions, last from one to four years, and are performed on 300 to 3,000 volunteers; and phase IV trials test safety and efficacy on several thousand volunteers ***after*** a drug has been approved by the FDA. *Id.*

in their blood for fuel. If left untreated DKA, can result in diabetic coma or death. DKA presents a much greater risk to people with T1d than people with T2d.

8. In 2015, Lexicon was preparing to begin phase 3 clinical trials of sotagliflozin as a treatment for T1d. The trials would be the last clinical trials before the Company sought FDA approval. Lexicon had arranged for three phase 3 trials to assess the safety and efficacy of sotagliflozin in approximately 3,000 adults with inadequately controlled T1d. Lexicon named the trials "inTandem1," "inTandem2" and "inTandem3" (the "Phase 3 Trials"). InTandem1 and inTandem2 tested 200 mg and 400 mg doses of sotagliflozin, while inTandem3 only tested 400 mg doses of the drug.

9. Defendants knew that if a substance incidence of DKA was found in the Phase 3 Trials in patients taking sotagliflozin, the FDA was likely to reject the drug due to safety concerns. This was because, among other things, Lexicon wanted to obtain approval for sotagliflozin as a treatment *for T1d*, and T1d sufferers are at a much a greater risk of DKA. Sotagliflozin would be the first-ever drug of its type approved for use in T1d sufferers. Defendants needed to find a way to downplay any incidence of DKA in the Phase 3 Trials. Defendants thus designed the Phase 3 Trials so that the results would emphasize sotagliflozin's benefits and downplay incidences of DKA.

10. To emphasize sotagliflozin's benefits, Defendants set the "primary endpoint"[2] of the inTandem1 and inTandem2 trials as the "change from baseline in HbA1c levels[3] of by week

[2] "Primary endpoints" of clinical trials are "[t]he specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment." *See* https://medical-dictionary.thefreedictionary.com/primary+endpoint.

[3] HbA1c levels are also known as "glycated hemoglobin," "glycosylated hemoglobin," "hemoglobin A1C" or "A1c" levels. HbA1c reflects the average glucose level in a patient's bloodstream over the prior two to three months and is determined by measuring what percentage

24 of the trial." Defendants then set the "secondary endpoint"[4] of those same trials as a "composite endpoint"[5] that measured the "*proportion* of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA." Defendants were so focused on downplaying incidence of DKA that they used the "composite endpoint" from inTandem1 and inTandem2 as the *primary endpoint* for the inTandem3 Phase 3 Trial.

11. The FDA had told Defendants, however, that the "composite endpoint" it planned to use in the Phase 3 Trials was likely to create misleading results in 2015, during meetings prior to the start of the Phase 3 Trials. Indeed the FDA warned Defendants about their use of the composite endpoint *at the very latest* by March 2018 since, in a presentation to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee on January 17, 2019, an FDA representative told committee members that "[d]uring *presubmission* meetings with the sponsor [*i.e.*, prior to March 26, 2018], the FDA expressed concern about the utility of the composite endpoint and *whether it would be adequate to characterize the overall benefit-risk*" of sotagliflozin. Jan. 17, 2019 Advisory Committee Meeting Transcript ("Comm. Tr.") 118:15–19. Although Defendants had actual knowledge that the FDA was not in favor of the composite endpoint used by Lexicon in its Phase 3 Trials, Defendants *never* disclosed that fact to investors.

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of the patient's hemoglobin in covered with glucose, or "glycated." The higher a patient's HbA1c test percentage, the higher their risk of diabetes complications. Whether a drug is shown to reduce HbA1c levels is a key factor in whether that drug will be approved to treat diabetes.

[4] "Secondary endpoints" are extra benefits of the treatment under study after it has been demonstrated that the primary endpoints show clinically meaningful benefits of the treatment.

[5] "Composite endpoint" are endpoints in clinical trials that consist of at least two or more distinct endpoints, called "component endpoints." In the Phase 3 Trials, Defendants' "composite endpoint" consisted of (i) patients who achieved an A1c of less than 7% and (ii) patients who did not have an episode of severe hypoglycemia or DKA.

12. Lexicon did not have the resources to complete the Phase 3 trials and obtain FDA approval of sotagliflozin on its own, so in November 2015, the Company entered into a collaboration and license agreement with Sanofi S.A. ("Sanofi"), a French multinational pharmaceutical company. Sanofi could terminate the agreement if a regulatory body found the risks associated with sotagliflozin so severe that Lexicon and Sanofi had to stop developing the drug, or if the drug failed to achieve positive results, *i.e.*, certain results at the endpoints of phase 3 clinical trials for T1d or T2d.

13. Although Defendants did their best to conceal the serious risk of DKA for patients taking sotagliflozin, the Phase 3 Trials revealed an ***eightfold increase of DKA for sotagliflozin users over placebo***. Defendants, however, never told the market that the Phase 3 Trials showed an ***eightfold increase*** in DKA in test subjects taking sotagliflozin.

14. To make matters worse, not only was there an eightfold increase in DKA, but virtually all of the incidences of DKA in the inTandem1 and inTandem2 trials were considered as "serious" under the applicable regulatory guidan***ce and over 68% of those incidences of DKA were assessed by the investigators conducting the trials to be "severe."***

15. The incidence of DKA also ***increased*** over the course of the 52-week trials in spite of Lexicon's efforts to identify and manage those incidences. For example, Lexicon instructed the investigators conducting the trials to closely monitor subjects for potential indicators of DKA, and gave test subjects expensive ketone testing strips and beta hydroxybuteric acid ("BHB") monitors, but none of these measures were effective in reducing the incidence of DKA. But the DKA that affected patients in the Phase 3 Trials was ***unique*** in that the symptoms that usually suggested the onset of DKA, like increased thirst or urination, ***were not reliable to detect DKA in patients taking sotagliflozin during the Phase 3 Trials***. This meant that patients had fewer early signs and

symptoms and had to rely on ketone tests to see if a DKA episode was imminent. Patients were also at a risk of DKA for longer periods while on sotagliflozin because the medication had a long "half-life," meaning it remained in the body for long periods of time, expanding the timeframe when DKA could develop. The incidence of DKA in the Phase 3 Trials was so evenly dispersed that Lexicon could not identify classes of patients that were at a greater risk of DKA on sotagliflozin. Defendants never disclosed any of these issues concerning DKA to investors.

16. If that were not bad enough, the Phase 3 Trials did not show that the effect that sotagliflozin was having on patients' HbA1c levels was *meaningful*. The Phase 3 Trials showed an average reduction in HbA1c levels for patients taking sotagliflozin of 0.3% to 0.4%. The target HbA1c level set by the American Diabetes Association ("ADA") for people with diabetes is 7% or lower. Over ***half of T1d sufferers*** have HbA1c levels over 8%, thus a decline of 0.3% to 0.4% would not reduce those T1d sufferers' HbA1c levels to anywhere near 7%. In addition, by reporting the *average* reduction in HbA1c, Defendants were potentially concealing the existence of a large number of insignificant declines in HbA1c, *e.g.*, from 7.0% to 6.9%, that were made to seem larger because of a small number of large decreases in an HbA1c in a patient with a high HbA1c level, *e.g.*, from 8.5% to 7.2%. The HbA1c declines reported in the Phase 3 Trials thus were not *meaningful*, and paled in comparison to the incidences of DKA.

17. Similarly, the average weight loss experienced by a patient on sotagliflozin, only 2 to 3 kilograms per patient, was less than 5% per patient and thus also *not* statistically meaningful. Finally, while patients in the inTandem1 and inTandem2 trials did see a decrease in hypoglycemia, a different life-threatening condition for diabetics that is caused by low blood sugar, incidence of hypoglycemia had *increased* over placebo in patients in the inTandem3 trial. Accordingly, there was ***no consistent trend for hypoglycemia*** across the Phase 3 Trials.

18. Defendants also touted that patients taking sotagliflozin spent more time inside a target glucose range (the "Time-in-Range" measurement) and had less glycemic variability (the "Glycemic Variability" measurement). Defendants did not disclose, however, that Time-in-Range and Glycemic Variability *had not been validated by the FDA for use in regulatory decision making for antidiabetic drugs*.

19. In sum, the increases in DKA, over two-thirds of which were assessed to be severe; the modest reductions in HbA1c and weight; and the inconclusive trend of hypoglycemia in the Phase 3 Trials provided strong evidence that the FDA would *not* approve sotagliflozin. Defendants, however, did not disclose this information to investors. Instead, Defendants used the Phase 3 Trials, which they had designed to conceal the risks posed by DKA, in a campaign to obtain FDA approval by misleadingly touting the purported benefits of sotagliflozin and concealing the risks of DKA.

20. Defendants made their materially false and misleading statements and/or omissions about sotagliflozin throughout the Class Period in SEC filings, press releases, presentations, and conference calls with investors and analysts. Their statements uniformly (i) concealed the stunning increases in DKA associated with sotagliflozin over placebo; (ii) failed to disclose that the FDA had warned against using the "composite endpoint" in the Phase 3 Trials, (iii) misrepresented the benefits of sotagliflozin; (iv) failed to disclose that the Time-in-Range and Glycemic Variability measures Lexicon touted were not validated for use in regulatory decision making for antidiabetic drugs; (v) failed to disclose that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the approval of sotagliflozin.

21. Defendants made these misrepresentations and omissions even though they had actual knowledge of the truth about incidence of DKA, the FDA's concerns about the "composite

endpoint," the limited benefits of sotagliflozin, the irrelevant Time-in-Range and Glycemic Variability measurements, and the woefully insufficient risk management plan because Lexicon was responsible for the clinical development of sotagliflozin for T1d under the Sanofi Agreement and received all the data directly from the investigators conducting the trials, the development of sotagliflozin was essential for the Lexicon's survival, and Defendants had designed the Phase 3 Trials to conceal the increased risk of DKA.

22. On the strength of Defendants' repeated misrepresentations and omissions concerning sotagliflozin, Sanofi, as sotagliflozin's "sponsor," filed a New Drug Application ("NDA") for sotagliflozin with the FDA on March 26, 2018 based on data from the Phase 3 Trials. The FDA accepted the NDA on May 22, 2018.

23. On November 26, 2018, the FDA announced that the Advisory Committee, a group of independent experts in endocrinology, metabolism, epidemiology or statistics, would hold a public meeting on January 17, 2019 to discuss sotagliflozin (the "Committee Meeting"). At the end of the meeting, the Advisory Committee would vote on whether "the available data suggest that the benefits outweigh the risks and support approval of sotagliflozin."

24. In advance of the Committee Meeting, Sanofi and the FDA each provided the Advisory Committee with briefing materials. The materials submitted by Sanofi regurgitated the misleading statements Defendants had made throughout the Class Period, emphasizing the modest declines in Hb1Ac levels and patient weight, claiming that there were fewer incidents of hypoglycemia, and touting that patients on sotagliflozin spent more Time-in-Range and had less Glycemic Variability. Lexicon's briefing materials did acknowledge the increases in DKA in patients taking sotagliflozin, but insisted that the risk could be managed with appropriate measures. The risk mitigation strategy described for sotagliflozin was one in which the drug would not be

indicated for patients with a higher risk of DKA, physicians and patients would receive materials on DKA, and patients would be advised to regularly check ketone levels.

25. The FDA's briefing materials, by contrast, emphasized the risk of DKA to patients taking sotagliflozin, and stated that "sotagliflozin therapy clearly increases that risk, and the risk may be unpredictable." The FDA also stated that it had "concerns about the clinical significance of the chosen composite" endpoint used by Lexicon, and suggested that the endpoint was not "a clinically meaningful way to frame both the benefits and the risks" of sotagliflozin.

26. At the Committee Meeting, on January 17, 2019, The FDA bluntly told the Committee that "sotagliflozin was associated with ***an approximately eightfold increase in DKA risk*** versus placebo," which was likely understated because "in the clinical trial setting, patients received ***intensive clinical monitoring***." *See* Comm. Tr. 144:3-14. The FDA also called out the misleading endpoint used by Defendants in the Phase 3 Trials, telling the Advisory Committee that "[s]ponsor defined net benefit [*i.e.*, composite endpoint] ***masked increased risk in DKA*** in sotagliflozin groups." *Id.* 126:2-7. In fact, the FDA told Committee Members that "we think the sponsor-defined [composite endpoint] . . . ***does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment***." *Id.* 127:14-18.

27. Several members of the Advisory Committee savaged sotagliflozin during the Committee Meeting, exposing Defendants' false and misleading statements about the drug. One member stated that "[w]e have ***small reductions in hemoglobin A1C***, ***small reductions in weight*** in a population where that's not a crisis, and we have ***no data to suggest that . . . patients feel better on this drug***." *Id.* 295:9-15. Another member noted that "it's not just that there is more DKA; ***it's the fact that it is more severe***." *Id.* 308:16-17. A third remarked that "it's impossible to understate the concern about DKA . . . ***the absolute increase is really remarkable for a***

condition," *id.* 309:20-310:3, and "it's impossible to think that it's not ***going to be worse in the real world***." 310: 8-10.

28. At the end of the Committee Meeting, the Advisory Committee deadlocked "eight to eight" on the question of whether the overall benefits of sotagliflozin outweighed the risks to support approval. All eight committee members who voted "no" pointed to the dramatic increase in DKA during the Phase 3 Trials, which Defendants had worked so hard to conceal, as outweighing the benefits of the drug. One committee member summed it up by saying, "we didn't get to hear from people who had DKA, and their life might have changed from that potentially life-threatening outcome. ***It's increased eightfold, which I couldn't get over***." Comm. Tr. 373:12–19.

29. The Committee Meeting was the first time that the market learned of (i) the full extent of the increase in DKA in patients taking sotagliflozin over patients taking placebo; (ii) that the FDA had specifically warned Defendants that the composite endpoint was not reliable, and hid the risk of DKA; (iii) that the benefits of sotagliflozin were only modest; (iv) that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs; and (v) that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the successful approval of sotagliflozin.

30. On news of the Advisory Committee's deadlock, and the disclosure of Defendants' materially false and misleading misrepresentations and omissions, Lexicon's stock price fell $1.74 per share, or 22.6%, to close at $5.96 per share on January 18, 2019.

31. On March 22, 2019, Lexicon announced that the FDA had issued a "Complete Response Letter" ("CRL") informing the Company that the FDA would not approve sotagliflozin. That day, on news of the CRL, Lexicon's stock price fell $1.74 per share, or 21.9%, to close at

$6.20 per share on March 22, 2019. Lexicon's stock price continued to fall over the next week as the market digested the FDA's refusal to approve sotagliflozin. The Company's stock price bottomed out on March 28 at $5.26 per share, a total decline of 33.8%.

32. The FDA's rejection of sotagliflozin severely curtailed the commercial potential of the drug, which now — if it was approved at all — would carry strongly worded warnings about the risk of DKA and might be beaten to the T1d market by a competing drug. In addition, the commercial potential of sotagliflozin in the T2d market was far weaker than its potential in the T1d market because other similar drugs had already been approved as T2d treatments and could be available as lower-priced generics before sotagliflozin reached the market.

33. The now-limited commercial potential of the drug led Sanofi to look for ways to terminate the Sanofi Agreement and end its commitment to Lexicon. On July 26, 2019, Sanofi disclosed that the top-line results for two phase 3 trials it was conducting on the efficacy of sotagliflozin as a treatment for T2d failed to achieve "statically significant reductions" in HbA1c, and that Sanofi was terminating the Sanofi Agreement.

34. Sanofi's termination of the Sanofi Agreement was clearly a result of the Advisory Committee's deadlocked vote, which led to the FDA's rejection of sotagliflozin. This was a materialization of the risk stemming from Defendants' false and misleading statements and/or omissions concerning sotagliflozin, which had already led to the Advisory Committee's deadlocked vote at the Committee Meeting and the FDA's decision not to approve sotagliflozin as a T1d treatment.

35. On news of Sanofi's termination the Sanofi Agreement, Lexicon's stock price fell ***$4.00 per share***, or ***70.3%***, to close at $1.69 per share on July 29, 2019.

36. The precipitous decline in the market value of Lexicon's securities was caused by Defendants' false and/or misleading statements and/or omissions that (i) concealed the stunning increases in DKA associated with sotagliflozin over placebo; (ii) failed to disclose that the FDA had warned against using the "composite endpoint" in the Phase 3 Trials, (iii) misrepresented the benefits of sotagliflozin; (iv) failed to disclose that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs; (v) failed to disclose that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the successful approval of sotagliflozin; and (vi) as a result, Lexicon's public statements were materially false and misleading at all relevant times. Plaintiff and other Class members have suffered significant losses and damages as a result of Defendants' misconduct.

37. Defendants made the misstatements and/or omissions with actual knowledge, or at the very least reckless disregard of their falsity because Defendants were responsible for all clinical development activities relating to sotagliflozin for T1d and thus knew the truth about the limited benefits and severe risks associated with the drug, the Company was hemorrhaging money and could not survive without FDA approval of sotagliflozin, and Defendants structured the endpoints of the Phase 3 Trials of sotagliflozin to hide the incidence and severity of DKA.

JURISDICTION AND VENUE

38. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

39. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

40. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Lexicon is headquartered in this District, Defendants conduct business in this District, and a significant portion of Defendants' actions took place within this District.

41. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

42. Plaintiff, as set forth in the Certification, acquired Lexicon's securities at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures.

43. Defendant Lexicon is a Delaware corporation with its principal executive offices located at 8800 Technology Forest Place, The Woodlands, Texas 77381. Lexicon's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "LXRX."

44. Defendant Lonnel Coats ("Coats") has been the President, the Chief Executive Officer ("CEO") and a Director of Lexicon since July 2014. Prior to joining Lexicon, he served in various leadership positions at Eisai Inc. and Eisai Corporation of North America (together, "Eisai") from 1996 to 2014. He was Eisai's CEO from 2010 to June 2014 and President and Chief Operating Officer from 2004 to 2010.

45. Defendant Jeffrey L. Wade ("Wade") has been Lexicon's Chief Financial Officer ("CFO") and Vice President – Corporate and Administrative affairs since February 2015. Prior to

that, he served as Lexicon's Executive Vice President ("EVP") – Corporate Development and CFO from May 2010 until February 2015.

46. Defendant Pablo Lapuerta ("Lapuerta") has been Lexicon's Executive Vice President and Chief Medical Officer since February 2015 and previously served in a series of medical and clinical leadership positions since joining the Company in 2011.

47. Defendants Coats, Wade and Lapuerta are sometimes referred to herein collectively as the "Individual Defendants."

48. The Individual Defendants possessed the power and authority to control the contents of Lexicon' SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

A. Background

49. Lexicon is a biopharmaceutical company that was founded in 1995 and is headquartered in The Woodlands, Texas. Lexicon focuses on the development and commercialization of pharmaceutical products for the treatment of human diseases. The company operates through a single business segment that engages in the discovery and development of pharmaceutical products.

50. At the start of the Class Period, on March 11, 2016, Lexicon filed its annual report on Form 10-K for the year 2015, which was signed by the Individual Defendants (the "2015 10-K"). That report disclosed, among other things, that Lexicon was "presently devoting most of our resources to the development of our two most advanced drug candidates." These drugs were "XERMELO," an oral treatment for carcinoid syndrome diarrhea, and sotagliflozin

51. At the start of the class period, XERMELO, was in phase 3 clinical trials, and the Company was preparing to submit the medication for FDA approval. Sotagliflozin, Lexicon's other "most advanced drug candidate," had begun Phase III clinical trials as a treatment for T1d.

52. Lexicon entered into a collaboration and license agreement for sotagliflozin with Sanofi. Under the Sanofi Agreement, Lexicon granted Sanofi an exclusive, worldwide, royalty-bearing right and license to develop, manufacture and commercialize sotagliflozin. Lexicon, however, was responsible for all clinical development activities relating to T1d and retained an exclusive option to co-promote and collaborate with Sanofi, in the commercialization of sotagliflozin for the treatment of T1d in the United States. Sanofi was responsible for all clinical development and commercialization of sotagliflozin for the treatment of T2d worldwide and was solely responsible for the commercialization of sotagliflozin for the treatment of T1d outside the United States. Sanofi could terminate the agreement if a regulatory body found the risks associated with sotagliflozin so severe that Lexicon and Sanofi had to stop developing the drug, or if the drug failed to achieve certain results at the endpoints of phase 3 clinical trials for T1d or T2d. Under the Sanofi Agreement, Lexicon also received a $300 million upfront payment under the agreement and was eligible to receive up to $430 million upon the achievement of specified development and regulatory milestones and up to $990 million upon the achievement of specified sales milestones.

53. Throughout the Class Period, Lexicon's financial position was precarious. Its 2015 10-K stated, for example, that the Company had accumulated a debt of ***$1.1 billion*** on revenues of only ***$130 million***, and this disparity widened substantially throughout the Class Period.

54. Lexicon's annual report on Form 10-K for 2016, which was filed with the SEC on March 6, 2017 (the "2016 10-K"), reported over ***$1.24 billion*** in debt compared with revenues of only ***$79.2 million***; the Company's annual report on Form 10-K for 2017, which was filed with the SEC on March 1, 2018 (the "2017 10-K"), reported over ***$1.36 billion*** in debt compared with revenues of only ***$91.6 million***; and the Company's annual report on Form 10-K for 2018, which was filed with the SEC on March 15, 2019 (the "2018 10-K"), reported over ***$1.47 billion*** in debt compared with ***$63.2 million*** in revenue.

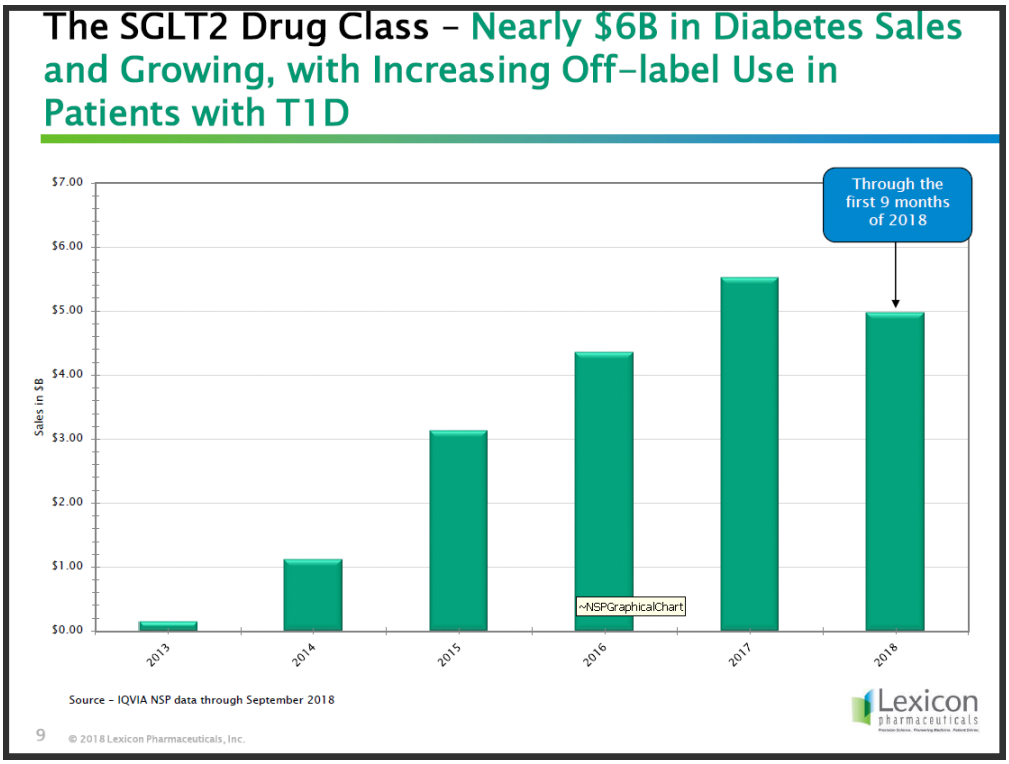
55. The $130 million in revenue the Company reported for 2015, which was ***by far*** the high water mark for the Company during the class period, was almost entirely attributable to the initial $300 million payment the Company received from Sanofi pursuant to the Sanofi Agreement. Indeed, the 2015 10-K had disclosed that ***98%*** of Lexicon's revenues were attributable to the payment from Sanofi. Even this influx of cash was not enough to make Lexicon profitable: the Company reported a losses of ***$4.7 million*** in 2015. The Company's losses then exploded after 2015, with the Company reporting losses of over $131 million in 2016, over $122 million in 2017 and over $120 million in 2018.

56. In addition, the Company's cash reserves had ***plummeted by 70%*** during the Class Period. Specifically, the 2015 10-K reported cash reserves of approximately $521 million, the 2016 10-K reported cash reserves of approximately $346 million, the 2017 10-K reported cash reserves of approximately $310 million, and the 2018 10-K reported cash reserves of only

approximately $160 million. As of March 31, 2019, the Company's cash had declined to only ***approximately $133 million***.

57. Both Defendants and investors knew that Lexicon would not be able to become profitable — or perhaps even survive — unless the FDA approved Lexicon's products. The only product in Lexicon's pipeline that presented any opportunity for profitability in the near term was sotagliflozin.

58. Defendants touted how FDA approval of sotagliflozin would be a financial windfall for the Company. At a September 2018 healthcare conference sponsored by Wells Fargo, Defendant Coats showed the following slide to attendees, which stated that the size of the market for SGLT-2 inhibitors (*i.e.*, drugs like sotagliflozin) had grown from well under $1 billion in 2013 to nearly $5 billion in the first 9 months of 2018, and implied that Lexicon would be able to access staggering revenues after sotagliflozin was approved:



At the same conference, Coats told attendees that "[w]e believe overall, the addressable market in type 1 is somewhere in the neighborhood of ***$5 billion***." Analysts shared Defendants' optimism: a Jefferies analyst had predicted that, if approved, sotagliflozin's sales could reach ***$1 billion annually***.[6]

59. Lexicon would make hundreds of millions of dollars from sales of sotagliflozin pursuant to the Sanofi Agreement. Each of the 10-Ks and 10-Qs filed with the SEC during the class period highlighted the financial boon that awaited Lexicon with the eventual commercialization of sotagliflozin as a treatment of type 1 diabetes:

> "***We received a $300 million upfront payment under the agreement and we are eligible to receive up to $430 million upon the achievement of specified development and regulatory milestones and up to $990 million upon the achievement of specified sales milestones. We are also entitled to tiered, escalating royalties ranging from low double digit percentages to forty percent of net sales of Sotagliflozin***, based on indication and territory, ***with royalties for the higher band of such range attributable to net sales for type 1 diabetes in the United States[.]***

60. To unlock those revenues and profits, however, Lexicon needed to obtain FDA approval of sotagliflozin as a treatment for T1d in the United States. Under the terms of the Sanofi Agreement, which Defendant Coats described for analysts and investors on a March 1, 2016 conference call, while the royalties Sanofi would pay Lexicon would be in the "***low double-digit percentages***" for sales of sotagliflozin abroad, they would rocket up "***to 40% of net sales, specifically in the U.S.*** and for type 1 diabetes."

61. Defendants also knew that obtaining FDA approval for sotagliflozin would transform the T1d treatment industry. For example, Jorge Insuasty, Senior-Vice President, Global

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[6] *See* Sagonowsky, E., *FDA Stiff-Arms Sanofi and Lexicon's Type 1 Diabetes Hopeful Zynquista*, FiercePharma, Mar. 22, 2019, https://www.fiercepharma.com/pharma/fda-rejects-sanofi-s-type-1-diabetes-hopeful-zynquista.

Head of Development, Sanofi, had told investors "[i]f approved, Zynquista would be the first oral antidiabetic drug approved in the U.S. for use by adults with type 1 diabetes, in combination with insulin."

B. Type 1 and Type 2 Diabetes

62. T1d is an autoimmune disease that renders T1d suffers unable to produce insulin. People who do *not* suffer from T1d break down carbohydrates into blood glucose (*i.e.*, blood sugar), and use insulin to transport that glucose from the bloodstream to cells where it is used for energy. T1d sufferers, however, produce little or no insulin because their bodies mistakenly attack the insulin-producing cells in the pancreas. Without insulin to transport glucose, glucose builds up in T1d sufferers' bloodstreams, which causes serious health problems.[7]

63. The ADA estimates that "1.25 million Americans have type 1 diabetes and an estimated 40,000 people will be newly diagnosed each year" in the United States.[8] Pharmaceutical industry analysts estimate that the market for T1d treatments will reach ***$25.52 billion by 2024***.[9]

64. There is no cure for T1d. Instead, sufferers treat their T1d by monitoring their glucose levels throughout the day and injecting insulin multiple times per day using insulin pens, syringes or an insulin pump.[10]

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[7] Mayo Foundation for Medical Education and Research ("Mayo"), *Type 1 Diabetes*, MayoClinic.org, https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/symptoms-causes/syc-20353011 (last visited July 30, 2019).

[8] *Id.*

[9] Press Release, Hexa Research, *Type 1 Diabetes (T1D) Market Size Worth USD 25.52 Billion by 2024*, Apr. 12, 2019, https://www.marketwatch.com/press-release/type-1-diabetes-t1d-market-size-worth-usd-2552-billion-by-2024-hexa-research-2019-04-12.

[10] *See* ADA, *Living with Type 1 diabetes*, http://www.diabetes.org/living-with-diabetes/recently-diagnosed/living-with-type-1-diabetes.html (last visited July 30, 2019).

65. People who suffer from T2d, on the other hand, produce insulin, but have developed a condition where their bodies do not use that insulin properly.[11] There is also no cure for T2d. Although some sufferers can manage T2d via diet and exercise, T2d usually gets worse over time and they eventually may be prescribed oral medications or insulin.[12]

66. T1d and T2d can be diagnosed using a variety of tests. One common blood test used to diagnose T1d and T2d, as well as to monitor both conditions, is a test of a patient's "HbA1c levels."[13] HbA1c levels are also known as "glycated hemoglobin," "glycosylated hemoglobin," "hemoglobin A1C" or "A1c" levels. HbA1c reflects the average glucose level in a patient's bloodstream over the prior two to three months and is determined by measuring what percentage of the patient's hemoglobin in covered with glucose, or "glycated." The higher a patient's HbA1c test percentage, the higher their risk of diabetes complications. Whether a drug is shown to reduce HbA1c levels is a key factor in whether that drug will be approved to treat diabetes.

67. A person who does not have diabetes, will have a "normal" HbA1c level below 5.7%. A person with an HbA1c level between 5.7% and 6.4% is said to have "prediabetes" and is at risk of developing diabetes in the future. A person with an HbA1c level of 6.5% or higher on two separate occasions has diabetes, and an HbA1c level over 8% indicates that the person's diabetes is not well-controlled and the person is at risk of diabetes complications. Over half of T1d sufferers have an HbA1c level ***over 8%***. Most diabetes sufferers, including T1d sufferers, aim for an HbA1c level of 7% or lower.

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[11] *See* ADA, *Type 2*, http://www.diabetes.org/diabetes-basics/type-2/ (last visited July 30, 2019).

[12] ADA, *Facts About Type 2*, http://www.diabetes.org/diabetes-basics/type-2/facts-about-type-2.html (last visited July 30, 2019).

[13] *See* Mayo Foundation, *A1C Test*, MayoClinic.org, https://www.mayoclinic.org/tests-procedures/a1c-test/about/pac-20384643 (last visited July 30, 2019).

68. T1d and T2d sufferers are at risk of a variety of complications stemming from their bodies' inability to move glucose from their blood to their cells. One of these complications is "hyperglycemia" or "high blood glucose," which occurs when there is too much glucose in the blood.[14] If left untreated, hyperglycemia can result in DKA. DKA is a serious, life-threatening condition that develops when diabetes sufferers do not produce enough insulin and their bodies are unable to use glucose in their blood for fuel.[15] Without glucose, diabetes sufferers begin to break down fats to use for energy, which results in a build-up of acids in the bloodstream called "ketones." The build-up of ketones causes DKA and, if left untreated, DKA can lead to diabetic coma or death. People with T1d are much more likely to experience DKA than people with T2d.[16]

C. Sodium-Glucose Co-transporter Inhibitors

69. According to Lexicon, sotagliflozin was developed by the Company's own chemists as a medication that inhibits two sodium-glucose cotransporters: sodium-glucose cotransporter type 1, or "SGLT-1," which is a protein that enables the body's the gastrointestinal tract to absorb glucose, and sodium-glucose cotransporter type 2, or "SGLT-2," a protein that performs the same function in the kidneys.[17] When the body's SGLT-1 and SGLT-2 proteins are operating normally, they enable the body to preserve glucose for use as energy that would

[14] ADA, *Hyperglycemia (High Blood Glucose)*, http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hyperglycemia.html (last visited July 30, 2019).

[15] Mayo Foundation for Medical Education and Research, *Diabetic Ketoacidosis*, MayoClinic.org, https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551 (last visited July 30, 2019).

[16] Fattah, H. & Vallon, V., *The Potential Role of SGLT2 Inhibitors in the Treatment of Type 1 Diabetes Mellitus*, Drugs 78:7 at 717–726 (May 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6429906/.

[17] *See* Schnur, M., *SGLT2 and SGLT1: What's the Difference?*, Lippincott NursingCenter, Nov. 26, 2018, https://www.nursingcenter.com/ncblog/november-2018/sglt2-and-sglt1.

otherwise be passed out of the body through urination. In theory, sotagliflozin would prevent the glucose filtered out by the body's gastrointestinal tract and kidneys from being reabsorbed into the body, which would pass out of the body via urination and lower a T1d patient's blood glucose.

70. In March 2013, the FDA approved Canagliflozin, a sodium-glucose cotransporter inhibitor that only worked to inhibit SGLT-2, for treatment of ***T2d***. SGLT-2 inhibitors, like Canagliflozin, however, are associated with serious incidences of DKA. The FDA grew so concerned by the incidences of DKA in diabetes sufferers that on May 15, 2015, only ***two months*** after approving Canagliflozin, it issued a public "Drug Safety Communication" warning of this risk of DKA to users of SGLT-2 inhibitors.[18] The FDA's warning stated that the FDA Adverse Event Reporting System ("FAERS") database had identified 20 cases of DKA in patients treated with SGLT-2 inhibitors from March 2013 to June 6, 2014, and that the FDA had continued to receive reports of DKA since.

71. On December 15, 2015, the FDA issued a follow-up Drug Safety Communication announcing that it was now requiring labels for all SGLT-2 inhibitors to include warnings about DKA.[19] The communication instructed patients to "pay close attention for any signs of ketoacidosis and seek medical attention immediately if they experience [ketoacidosis] symptoms." It further instructed healthcare professionals to "evaluate for the presence of acidosis, including ketoacidosis, in patients experiencing these signs or symptoms; discontinue SGLT2 inhibitors if acidosis is confirmed; and take appropriate measures to correct the acidosis and monitor sugar levels."

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[18] FDA, *FDA Warns that SGLT2 Inhibitors for Diabetes May Result In a Serious Condition of Too Much Acid in the Blood*, May 15, 2015.

[19] FDA, *FDA Revises Labels of SGLT2 Inhibitors For Diabetes to Include Warnings About Too Much Acid in the Blood and Serious Urinary Tract Infections*, Dec. 15, 2015.

D. Phase 3 Clinical Trials of Sotagliflozin

72. In 2015, Lexicon was preparing to begin phase 3 clinical trials of sotagliflozin as a treatment for T1d. The trials would be the last clinical trials before the Company sought FDA approval. Lexicon had arranged for three phase 3 trials to assess the safety and efficacy of sotagliflozin in approximately 3,000 adults with inadequately controlled T1d. Lexicon named the trials "inTandem1," "inTandem2" and "inTandem3" (the "Phase 3 Trials"). InTandem1 and inTandem2 tested 200 mg and 400 mg doses of sotagliflozin, while inTandem3 only tested 400 mg doses of the drug.

73. The inTandem1 and inTandem2 trials began with a 24-week double-blind treatment period, which was followed by a 28-week extension period. In addition, both trials enrolled T1d patients who at the time they were screened had HbA1c levels between 7% and 11%, although at the time the trials began, there was no limit on their HbA1c levels. The trials enrolled patients with a history of DKA, as long as the patients had not experienced DKA in the four weeks prior to screening and had no more than 2 episodes of DKA in the prior 6 months.

74. Defendants knew that prior phase 2 trials suggested that sotagliflozin was associated with the occurrence of DKA. Based on the FDA's statements of concern about the incidence of DKA in SGLT-2 inhibitors, Defendants knew that significant incidences of DKA could cause the FDA to not approve the drug because DKA was so substantial a health risk for diabetes sufferers. To make matters worse, Lexicon was seeking approval for sotagliflozin as a treatment *for T1d*, and T1d sufferers are at a much a greater risk of DKA. Defendants thus had to conceal the increased risk of DKA to patients taking sotagliflozin, otherwise the FDA would not approve the drug and Lexicon might not survive.

75. Defendants decided to design the Phase 3 Trials so that the results would over-emphasize sotagliflozin's benefits and downplay the risks of DKA. For example, to put the

maximum emphasis on sotagliflozin's benefits, Defendants set the "primary endpoint" of the inTandem1 and inTandem2 trials as the "change from baseline in HbA1c by week 24 of the trial." In other words, as long as HbA1c levels had declined by a certain amount by the end of the trials, the trials had obtained positive results *regardless of the incidence of DKA*.

76. Defendants then designed a "secondary endpoint"[20] for the inTandem1 and inTandem2 trials as a "composite endpoint" that measured the "proportion of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA." The composite endpoint thus focused on *the number of patients that had HbA1c under 7%* and did not discuss the incidence of DKA other than in the context of how many *more* patients were benefitting from the drug than had experienced the catastrophic, life-threatening condition. Defendants were so enamored with this composite endpoint that they used it as the *primary endpoint* for the inTandem3 Phase 3 Trial.

77. Defendant Coats assured analysts and investors that Lexicon had tailored the Phase 3 Trials to address the FDA's concerns about the safety and efficacy of sotagliflozin, telling attendees on a March 4, 2015 call with investors to report Lexicon's financial performance for the full year 2014 that, "The key is to stay focused on type 1 diabetes, which is where we are and be able to answer all the other questions that [the FDA] have for us, in terms of being able to show the balance of safety and efficacy, as these studies roll forward, ***and we have structured these studies to achieve that***." Defendants did not disclose, however, that this meant that the studies were designed to emphasize the benefits of sotagliflozin and hide the occurrence of DKA.

[20] "Secondary endpoints" are extra benefits of the treatment under study after it has been demonstrated that the primary endpoints show clinically meaningful benefits of the treatment.

78. The FDA told Defendants that the "composite endpoint" it planned to use in the Phase 3 Trials *was likely to create misleading results.* The FDA likely told Defendants this *in 2015, prior to the start of the Phase 3 Trials*, or, at the very latest, by March 2018. Indeed, in a presentation to the FDA's Endocrinologic and Metabolic Drugs Advisory Committee on January 17, 2019, an FDA representative said that "[d]uring *presubmission* meetings with the sponsor [*i.e.*, prior to March 26, 2018], the FDA expressed concern about the utility of the composite endpoint and *whether it would be adequate to characterize the overall benefit-risk*" of sotagliflozin. Jan. 17, 2019 Advisory Committee Meeting Transcript ("Comm. Tr.") 118:15–19. In other words, Defendants had actual knowledge that the FDA was concerned with the composite endpoint used by Lexicon in its Phase 3 Trials, which significantly affected the likelihood that the FDA would approve the drug, but *never* disclosed that fact to investors.

E. Results of the Phase 3 Trials

79. Incidences of DKA exploded during the Phase 3 Trials. Indeed, materials created by the FDA summarizing the results of the Phase 3 Trials revealed that there had been an ***eightfold increase of DKA for sotagliflozin users over placebo***.

80. Not only did the Phase 3 Trials reflect a dramatic increase in DKA for patients taking sotagliflozin, but the inTandem1 and inTandem2 trials showed that virtually all of the incidences of DKA qualified as "serious," as defined by regulatory guidance, and ***over 68% of the instances were assessed by trial investigators to be severe***.

81. The incidence of DKA also ***increased*** over the course of the 52-week trials and continued to increase in spite of Lexicon's efforts to identify and manage those incidences. For example, Lexicon instructed investigators conducting the trials to closely monitor subjects for potential indicators of DKA, and gave test subjects expensive ketone testing strips and BHB monitors so that patients could check for signs of DKA, but none of these measures were effective

in limiting the incidence of DKA. But the DKA that affected patients in the Phase 3 Trials was ***unique*** in that the symptoms that usually suggested the onset of DKA, like increased thirst or urination, ***were not reliable to detect DKA in patients taking sotagliflozin during the Phase 3 Trials***. This meant that patients had fewer early signs and symptoms and had to rely on ketone tests to see if a DKA episode was imminent. Patients were also at a risk of DKA for longer periods while on sotagliflozin because the medication had a long "half-life," meaning it remained in the body for long periods of time, expanding the timeframe when DKA could develop. The incidence of DKA in the Phase 3 Trials was so evenly dispersed that Lexicon could not identify classes of patients that were at a greater risk of DKA on sotagliflozin. Defendants never disclosed any of these issues concerning DKA to investors.

82. To make matters worse, the effect that sotagliflozin was having on patients' HbA1c levels was not meaningful. The Phase 3 Trials only showed an average reduction of HbA1c for patients taking sotagliflozin of ***0.3% to 0.4%***, and an average weight loss of 2 to 3 kilograms per patient. Since over half of people with T1d have HbA1c levels over 8%, a decline of 0.3% to 0.4% would not have a substantial effect on T1d sufferers, who generally hope to achieve HbA1c levels of 7%.[21] In addition, by reporting the *average* reduction in HbA1c, the Phase 3 Trials were potentially concealing the existence of a large number of insignificant declines in HbA1c, *e.g.*, from 7.0% to 6.9%, with a small number of large decreases in an HbA1c in a patient with a high HbA1c level, *e.g.*, from 8.5% to 7.2%. Since the HbA1c declines reported in the Phase 3 Trials were not *meaningful*, they were not likely to outweigh the extraordinary risk to patients posed by the increase in DKA.

[21] Defendants repeatedly told investors in earnings presentations and at conferences throughout the class period that the American Diabetes Association set a target for people with T1d of an HbA1c level of 7% or below, but that over half of T1d sufferers have an A1C greater than 8%.

83. Similarly, the average weight loss experienced by a patient on sotagliflozin was less than 5% per patient, which also was *not* statistically meaningful. Finally, while patients in the inTandem1 and inTandem2 trials did see a decrease in hypoglycemia, a different life-threatening condition for diabetics that is caused by low blood sugar, incidence of hypoglycemia had *increased* over placebo in patients in the inTandem3 trial.

84. In short, the sotagliflozin Phase 3 Trials showed a spike in incidences of DKA that were severe, difficult to identify and respond to, and resistant to Defendants' attempts to manage them. In addition, the spike in DKA had occurred in a tightly regulated clinical trial setting, which strongly suggested that the rate of DKA was actually ***understated*** compared to what would occur when the drug was marketed commercially. Finally, the relatively low benefits that some patients experienced were unlikely to be seen as outweighing the risks presented by the drug.

85. In sum, the increases in DKA, over two-thirds of which were assessed to be severe; the modest reductions in HbA1c and weight; and the inconclusive trend of hypoglycemia in the Phase 3 Trials provided strong evidence that the FDA would *not* approve sotagliflozin. Defendants, however, did not disclose this information to investors. Instead, Defendants used the Phase 3 Trials, which they had designed to conceal the risks posed by DKA, in a campaign to obtain FDA approval by misleadingly touting the purported benefits of sotagliflozin and concealing the risks of DKA.

F. Defendants Tout the Performance of Sotagliflozin in the Phase 3 Trials

86. Defendants had actual knowledge of the substantial increase in incidences of DKA, the severity and complicating factors attendant to those incidences of DKA, and the comparatively slight reductions of HbA1c and weight loss, that occurred in the Phase 3 Trials throughout the Class Period.

87. Defendants publicly disclosed top-line primary efficacy endpoint data for the inTandem1 trial in September 2016 and additional data in May 2017; top-line primary efficacy endpoint data for the inTandem2 trial in December 2016 and additional data in August 2017; top-line data for the inTandem3 trial in June 2017; and pooled data for the inTandem1 and inTandem2 clinical trials in September 2017. These disclosures consisted of, among other things, changes in patients' HbA1c levels, weight loss, incidences of hypoglycemia and incidences of DKA. Although Defendants publicly disclosed the Phase 3 Trial results in September 2016, December 2016, May 2017, August 2017 and September 2017, they obtained, and thus had actual knowledge of, the Phase 3 Trial results in advance of these public disclosures.

88. After receiving the data, rather than disclose the truth about sotagliflozin to investors, Defendants began a campaign designed to emphasize its modest benefits while concealing its risks. For example, in a September 9, 2016 press release reporting top-line results from the inTandem1 trial, Defendant Coats boasted to investors that "[w]e believe these results provide evidence that sotagliflozin, with its novel dual inhibition of both SGLT-1 and SGLT-2, ***is particularly well suited to help these individuals achieve better A1C levels without increasing and possibly reducing the risk of severe hypoglycemia***." In the same press release, Lexicon published a statement from the chairperson of the Sotagliflozin Type 1 Diabetes Steering Committee, an academic steering committee collaborating with Lexicon on the Phase 3 Clinical Trials (the "Steering Committee") said, "Sotagliflozin demonstrated compelling, significant and clinically meaningful A1C reduction with no increase in severe hypoglycemia and ***a slight risk of DKA***." Defendants made or published these statements even though the inTandem1 trial showed that sotagliflozin was not well suited to help patients achieve better HbA1c levels because patients taking the drug had more incidences of DKA that were severe, not accompanied by the typical

warning signs of an onset of DKA and unaffected by the risk mitigation steps taken by trial investigators. In addition, claiming that sotagliflozin was accompanied by a "slight" risk of DKA was grossly misleading, since incidences of severe DKA that occurred with little warning were piling up during the trials.

89. Further, as more results showing the dramatic increase in incidences of DKA when compared with placebo rolled in, Defendant Coats boasted, in a June 9, 2017 press release reporting results from the inTandem3 trial, that "Sotagliflozin is the first-ever oral anti-diabetic drug candidate ***to have achieved success*** in now three consecutive Phase 3 clinical trials in this population." This statement was misleading because it strongly implied that meeting the composite endpoint was an indication that the drug was safe and effective, when Defendants had failed to disclose that they had designed the composite endpoint to hide the risks of sotagliflozin and had been warned by the FDA against using the composite endpoint.

90. Defendants also sought to emphasize the modest benefits of sotagliflozin while concealing its risks by describing in detail reductions in HbA1c levels experienced by patients in the Phase 3 Trials and making only cursory references to incidences of DKA. For example, Defendants' disclosure of the results of the inTandem1 trial stated that:

> We reported top-line primary efficacy endpoint data in September 2016 and additional data in May 2017 from our pivotal inTandem1 Phase 3 clinical trial evaluating the safety and tolerability of sotagliflozin and its effects on glycemic parameters associated with type 1 diabetes.
>
> * * *
>
> Data from the study showed that patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.43% for the 200mg dose ($p<0.001$) and 0.48% for the 400mg dose ($p<0.001$), as compared to a reduction of 0.07% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint at both dose levels. The A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses. Benefits in all secondary efficacy endpoints were observed in both the 200mg and 400mg dose

> arms compared to placebo, with statistically significant improvements in all secondary efficacy endpoints observed in the 400mg dose arm and in the percentage of patients achieving A1C levels of less than 7% without any severe hypoglycemia or DKA events and weight loss observed in the 200mg dose arm and statistically significant improvements in all secondary efficacy endpoints observed in the 400mg dose arm.
>
> * * *
>
> The number of patients with positively adjudicated DKA events during the full 52-week treatment period was 1 (0.4%), 9 (3.4%) and 11 (4.2%) in the placebo, 200mg and 400mg dose arms, respectively.

91. Similarly, Defendants' disclosure of the results of the inTandem2 trial stated that:

> We reported top-line primary efficacy endpoint data in December 2016 and additional data in August 2017 from our pivotal inTandem2 Phase 3 clinical trial evaluating the safety and tolerability of sotagliflozin and its effects on glycemic parameters associated with type 1 diabetes.
>
> * * *
>
> Data from the study showed that patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.39% for the 200mg dose ($p<0.001$) and 0.37% for the 400mg dose ($p<0.001$), as compared to a reduction of 0.02% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint at both dose levels. The A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses. Statistically significant improvements in all secondary efficacy endpoints were observed in both the 200mg and 400mg dose arms compared to placebo.
>
> * * *
>
> The number of patients with positively adjudicated DKA events during the full 52-week treatment period was 0 (0.0%), 6 (2.3%) and 9 (3.4%) in the placebo, 200mg and 400mg dose arms, respectively.

92. Defendants' disclosure of the results of the inTandem3 trial also hyped the purported benefits of the sotagliflozin while downplaying the incidences of DKA:

> We reported top-line data in June 2017 from our inTandem3 Phase 3 clinical trial evaluating the safety and tolerability of sotagliflozin and its effects on glycemic parameters associated with type 1 diabetes.
>
> * * *

> Data from the study showed statistically significant superiority of sotagliflozin (28.6%) compared to placebo (15.2%) in the proportion of patients achieving A1C levels of less than 7% without experiencing a severe hypoglycemic or DKA event ($p<0.001$), meeting the study's primary endpoint. Patients treated with sotagliflozin also experienced statistically significant improvements in all secondary efficacy endpoints compared to placebo.
>
> * * *
>
> The number of patients with positively adjudicated DKA events during the 24-week treatment period was 4 (0.6%) and 21 (3.0%) in the placebo and 400mg dose arms, respectively. Results from the inTandem3 trial were published in the New England Journal of Medicine in September 2017.

93. The disclosures in ¶¶ 90–92 were materially misleading and omitted material facts because they touted the purported benefits of sotagliflozin, *i.e.*, reductions in HbA1c (the "primary and multiple secondary endpoints"), but did not disclose that the declines were not meaningful in patients with HbA1c levels over 8% (*i.e.*, half of T1d sufferers). Moreover, Defendants' disclosure of the *number* of incidences of DKA was materially misleading because Defendants did not note that these incidences represented increases in DKA of several multiples over placebo and omitted that the incidences were severe, increasing throughout the testing period and occurring without the normal symptoms that patients use to recognize the potential onset of DKA. Defendants also failed to disclose that their rudimentary risk mitigation plan of instructing the investigators conducting the trials and patients participating in the trials to be on the lookout for DKA was not effective in reducing the incidence of DKA.

94. Defendants also went out of their way to emphasize sotagliflozin's performance in the Time-in-Range metric:

> We reported pooled continuous glucose monitoring, or CGM, data in September 2017 from the inTandem1 and inTandem2 clinical trials. The percentage of time during the initial 24-week treatment period ***spent inside the target range*** for ***CGM glucose (70-180 mg/dL) increased*** from 52.2% to 57.8% in patients treated with 200mg of sotagliflozin and from 50.7% to 64.1% in patients treated with 400mg of sotagliflozin, with no relevant change observed in patients receiving placebo. The differences from placebo were clinically significant for both the 200mg and 400mg

> dose groups (p=0.026 and p<0.001, respectively). The ***increase in time spent in range*** by both sotagliflozin dose groups was a result of significantly reduced time spent above 180 mg/dL, while the time spent below 70 mg/dL was not increased. ***These results translate into an additional 1.41 hours and 3.02 hours that a patient would spend within the 70-180 mg/dL target range in a 24-hour period,*** for the 200mg and 400mg dose groups respectively.

95. This statement about the Time-in-Range measure was misleading because Defendants did not disclose that Time-in-Range had not been validated by the FDA for use in regulatory decision making for antidiabetic drugs health risks.

96. Defendants had actual knowledge that the statements they were making about the performance of sotagliflozin in the Phase 3 Trials were misleading because Lexicon was responsible for the clinical development of sotagliflozin for T1d under the Sanofi Agreement, had met with FDA officials and had received data directly from the investigators conducting the trials, the development of sotagliflozin was essential for the Lexicon's survival, and Defendants had designed the Phase 3 Trials to conceal the increased risk of DKA.

97. In addition, confidential witnesses who worked for Defendants corroborated Defendants' knowledge of the problems with sotagliflozin in the Phase 3 Trials. CW1, for example, was the receptionist at Lexicon's headquarters in The Woodlands, Texas, from July 2015 to February 2018. Although CW1 was the receptionist, he performed work for all of Lexicon's departments. CW1 participated in the submission of sotagliflozin to the FDA because she (i) attended at least two mock presentations in the second half of 2017 at Lexicon that were trial runs of what Defendants and Sanofi would present to the FDA regarding the forthcoming NDA for sotagliflozin, and (ii) performed research on DKA and hypoglycemia for Defendants and other Lexicon and Sanofi employees to use in addressing the FDA's concerns about those conditions. CW1 described how she received explicit, detailed instructions on what she could and could not say about sotagliflozin to individuals entering or leaving Lexicon's headquarters. Lexicon

required CW1 to practice her responses to questions from hypothetical individuals entering or leaving Lexicon's headquarters.

98. CW1 said that the mock presentations indicated that there were problems with sotagliflozin. Executives at Lexicon stormed out of the presentations screaming, "[t]he research isn't there. This is going to hell!" CW1 also recalled that members of Lexicon's research department told her that sotagliflozin "is going to be tough. This one is going to be harder to get through." They also said that, "XERMELO was easy, sotagliflozin is going to be hard."

99. Similarly, CW2 was a Vice President for Sales at Lexicon from 2016 to 2017. CW2 participated in a quarterly call in 2017, in which sotagliflozin was discussed with representatives of the European Association for the Study of Diabetes. CW2 said that incidences of DKA in the Phase 3 Trials were discussed on the call, and that he believed Lexicon as "spinning" the incidences of DKA, including by highlighting how the setting of the Phase 3 Trials could have contributed to the incidence of DKA.

G. Lexicon and Sanofi Seek FDA Approval of Sotagliflozin

100. On March 26, 2018, Lexicon announced that Sanofi had submitted a new drug application ("NDA") to the FDA for sotagliflozin. The NDA sought approval for sotagliflozin "as an adjunct to insulin in adults with type 1 diabetes," for two proposed doses: 200 mg and 400 mg, both given once daily, based on from the Phase 3 Trials. By filing the NDA, Sanofi was the "sponsor" of sotagliflozin. On May 22, 2018, Lexicon issued a press release announcing that the FDA had accepted Sanofi's NDA.

101. On November 26, 2018, the FDA announced that the Advisory Committee, a group of independent experts in the fields of endocrinology, metabolism, epidemiology or statistics, would hold a public meeting on January 17, 2019 to discuss the NDA (the "Committee Meeting"). During the Committee Meeting, representatives of Sanofi, as sotagliflozin's sponsor, and the FDA

would make PowerPoint presentations to the Advisory Committee on the benefits and risks of sotagliflozin. At the end of that meeting, the Advisory Committee would vote as to whether "the available data suggest that the benefits outweigh the risks and support approval of sotagliflozin." Although the Advisory Committee's decision is not binding on the FDA, it was very unlikely that the FDA would approve a drug that the Advisory Committee did not recommend.

102. In preparation for the January 17, 2019 Advisory Committee Meeting, both Lexicon (through Sanofi as the "sponsor" of sotagliflozin) and the FDA submitted briefing documents for the Advisory Committee to review. In advance of the Committee Meeting, both Sanofi and the FDA each provided the committee with briefing materials that ran 150 pages or more. The briefing documents provided by Lexicon differed strikingly in their presentation of the risks and benefits of sotagliflozin.

103. Lexicon's briefing materials, characterized the results of the Phase 3 Trials as showing that sotagliflozin "added to standard-of-care insulin and glucose management, consistently and significantly reduced A1c compared to placebo without increasing the risk of severe hypoglycemia." Lexicon's briefing materials also went on to say that reductions in HbA1c "occurred in conjunction with improvements in measures of day-to-day blood glucose variability [i.e., Glycemic Variability], treatment satisfaction and diabetes distress" and "without the weight gain caused by intensification of insulin treatment." Finally, Lexicon's briefing materials acknowledged that "sotagliflozin increases the risk of DKA," but insisted that the risk could be "managed with appropriate measures."

104. Lexicon's briefing materials also proposed the most rudimentary risk mitigation program to address in incidence of DKA. The program proposed consisted of recommending to physicians that they carefully screen patients at a higher risk of DKA, and offering literature to

patients asking them to be on the lookout for the symptoms of DKA, check their ketone levels, especially if they had been ill, had been fasting, or if their insulin dosing had been interrupted, and to contact their healthcare providers if their ketone were positive or if their condition did not improve. The program also suggested that literature would be available for patients to access online.

105. The FDA's briefing materials, however, emphasized the risk of DKA to patients taking sotagliflozin, and stated that "sotagliflozin therapy clearly increases that risk, and the risk may be unpredictable." The FDA also emphasized that it had "concerns about the clinical significance of the chosen composite" endpoint used by Lexicon, and suggested that the endpoint was not "a clinically meaningful way to frame both the benefits and the risks" of sotagliflozin.

106. The FDA's briefing materials also highlighted that the agency had consulted a database of incidences of DKA in T1d patients who had received off-label prescriptions for SGLT-2 inhibitors that had been approved for use in treating T2d. The FDA's briefing materials stated that the agency's review of off-label prescriptions of SGLT-2 inhibitors showed a ***greater*** incidence of DKA in patients than what was reflected in Lexicon's Phase 3 Trials, which suggested that the Phase 3 Trials were understating the incidence of DKA. Defendants had actual knowledge that DKA occurred more frequently in off-label prescriptions of SGLT-2 inhibitors than in the Phase 3 Trials because their own safety expert cited a study of approved SGLT-2 inhibitors used on T1d patients during the Advisory Committee Meeting and said that they studies provided "important insights into the safety of these drugs." Comm. Tr. 72:9-20, 74:20-75:1.

107. Finally, the FDA wrote in its briefing materials that while the Time-in-Range and Glycemic Variability results are "valued by patients and may relate to at least short-term improvements in quality of life and treatment satisfaction, these ***do not have an established***

relationship with long-term macrovascular and microvascular complications and ***have not been validated for use in regulatory decision making for antidiabetic drugs***." In other words, sotagliflozin's performance with regard to Time-in-Range and Glycemic Variability was *irrelevant* as to whether the Advisory Committee voted that the benefits of sotagliflozin outweighed the risks or whether the FDA ultimately approved the drug.

108. In other words, the FDA's briefing materials suggested that the composite endpoint Lexicon used in the Phase 3 Trials was not a meaningful way to frame the benefits and risks of sotagliflozin.

H. The Advisory Committee Deadlocks on Sotagliflozin Vote

109. The Advisory Committee met on January 17, 2019, from 8:15 AM to 4:44 PM, in Silver Spring, Maryland to discuss the application for approval of sotagliflozin. Sixteen voting members of the Advisory Committee were present, as well as three non-voting members. The minutes for the Advisory Committee Meeting (the "Advisory Committee Minutes") were certified by LaToya Bonner, the Advisory Committee's designated federal officer, and Peter Wilson, the Advisory Committee chairperson. The Advisory Committee Minutes were approved on February 21, 2019. A transcript of the Advisory Committee meeting is publicly available ("Advisory Committee Transcript" or "Comm. Tr.").

110. As described in the Advisory Committee Minutes and the Advisory Committee Transcript, the Committee opined on the following four issues during the meeting:

1. "[T]he benefits claimed by the applicant, e.g., glycemic control, effects on body weight and risk for hypoglycemia, for patients with type 1 diabetes."
2. The members' "level of concern about the observed risk of diabetic ketoacidosis (DKA) in adult patients in the Sotagliflozin clinical studies and DKA risk associated with sotagliflozin use in a real-world setting."
3. "Any relevant differences in efficacy and/or safety observed between two proposed doses of sotagliflozin (200 mg and 400 mg)."

4. "The overall benefit risk profile of sotagliflozin for patients with type 1 diabetes." Comm. Tr. 27:8–28:19.

111. The Advisory Committee began by discussing the benefits of sotagliflozin that Lexicon and Sanofi had claimed that the drug offered, specifically "glycemic control [i.e., reduction in Hb1Ac], effects on body weight, and risk for hypoglycemia, for patients with type 1 diabetes." *Id.* 27:8–11.

112. The Advisory Committee's show that the Committee identified a number deficiencies in the results of the Phase 3 tests. For example, the members "questioned the clinical relevance of the modest reduction in hemoglobin A1c (HbA1c) shown with sotagliflozin," and "discussed that the sotagliflozin development program lacked adequate quality of life (QOL) measurements that would have provided data on how the patients felt during the trial." Finally, one member specifically noted that "since it is unknown what the absolute risk reduction associated with HbA1c reductions is, [the Committee did not] know how to interpret the benefit with regard to prevention of diabetic related comorbidities, specifically microvascular diseases, e.g., retinopathy, nephropathy." Another member specifically noted that the degree of weight loss reported was small and would not be considered clinically meaningful for an obesity drug.

113. The Committee Members also "expressed great concern about the observed risk of diabetic ketoacidosis (DKA) in the phase 3 studies." The members cited "the number of observed DKA events relative to placebo in the phase 3 studies and the probability that the risk could be even higher in the real-world setting outside the confines of a clinical trial," and noted that there was no evidence the risk mitigation strategy proposed by the applicant works. The committee members also expressed concerns regarding the approval of sotagliflozin due to the DKA risk, ***and lack of clarity with regard to favorable benefits*** to balance against this substantial risk. Finally, the committee agreed that the primary composite endpoint data used by the applicant ***was not***

informative to weigh the increased risk of a life-threatening event against the benefit. Even the Committee Members who were in favor of a 200 mg dose expressed reluctance to recommend approval of the 400 mg dose due to its association with increased incidences of DKA and other problematic conditions.

114. During the safety presentation portion of the Advisory Committee Meeting, Sanofi admitted that "[e]vents leading to discontinuation" (i.e., that led to trial subjects stopping the use of sotagliflozin), "were more frequent with sotagliflozin, and DKA was the most common event leading to sotagliflozin withdrawal." Comm. Tr. 67:3-5. Sanofi also admitted that "[t]he incidence of serious events was also higher with sotagliflozin," and "DKA was the most common serious adverse event," while hypoglycemia was the most common SAE with placebo. *Id.* 67:6-10.

115. Sanofi also acknowledged that typical indicators of DKA (increased thirst or urination) were not reliable to detect emerging DKA and thus that patients "have less early signs and symptoms to detect emerging DKA and must rely on ketosis-related signs and symptoms" including tests for the presence of ketones. *Id* 69:1-6. In addition, Sanofi told the Advisory Committee that "ketone testing should start at lower glucose levels than typical for what is currently done in type 1 diabetes." *Id.* 72:4-8. Sanofi also admitted that it had tried to identify specific types of patients that were at a greater risk of DKA on sotagliflozin, but that "[n]o subgroup was identified in which a substantial increase in DKA risk was seen as compared to the study population as a whole." *Id.* 74:4-8.

116. In the FDA's presentation to the Advisory Committee, it noted that "[d]uring pre-submission meetings with the sponsor, the FDA expressed concern about the utility of the composite endpoint and whether it would be adequate to characterize the overall benefit-risk." *Id.*

118:15-19. In other words, the FDA had told Defendants previously that their "composite endpoint" was likely misleading.

117. The FDA also harshly criticized Defendants' use of the composite endpoint, telling the Advisory Committee that "[r]eductions in HbA1c, severe hypoglycemia, and DKA, are of different clinical importance, but ***when they were lumped together, the increased risk in a more severe but less frequent component, DKA, would be hidden*** . . . . [s]ponsor defined net benefit masked increased risk in DKA in sotagliflozin groups." *Id.* 126:2-7. In addition, when the FDA had reformatted the data to account for Defendant's attempt to conceal the incidences of DKA, the found "***the hidden trend*** . . . . [M]ore subjects experienced DKA events in the sotagliflozin groups compared to placebo. ***And this trend is more obvious in subjects with HbA1c greater than or equal to 7% in DKA*** . . . . [T]his trend of increased DKA risk in the sotagliflozin groups remained when the component of severe hypoglycemia was included. *Id.* 127:3-12. In addition, the FDA found that "[t]he rate of DKA continued to increase for the sotagliflozin group throughout the trial while the rate for placebo remains flat." *Id.* 138:13-15. The FDA concluded, "***we think the sponsor-defined net benefit endpoint masked the increased risk of DKA in the sotagliflozin groups and does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment***." *Id.* 127:14-18.

118. The FDA also noted that "the overall supervision of patients [in the Phase 3 Trials] was more intensive than in clinical practice. The recommendation to consume carbohydrates along with insulin in order to avoid hypoglycemia is also unique in comparison to typical management of DKA. Patients also had access to investigators around the clock, which may not be the same outside of a clinical trial setting." *Id.* 135:13-21.

119. The FDA also emphasized that Defendants' attempts to reduce the incidence of DKA during the trials had completely failed. For example, the FDA told the Advisory Committee that "[a]s a general point in all three studies, routine home ketone monitoring was at times not performed by patients, or was performed and found to be normal in the morning, but by afternoon had rapidly increased, thus making the utility of home ketone monitoring unclear. *Id.* 142:19-143:2. In addition, "sotagliflozin does not have a short half-life, so stopping the drug in the setting of acute illness may be too late." *Id.* 173:14-17. "Excess DKA was [also] robustly demonstrated in the phase 3 trials, and the intensive monitoring procedures that were used in the trials still did not reduce the risk of DKA to that of the placebo group." *Id.* 173:18-22. "In the real-world setting with approved SGLT-2 inhibitors, DKA rates were higher. We anticipate similar findings with sotagliflozin could be realized in the postmarket setting, where patients would not be followed as closely as they are in a clinical trial setting." *Id.* 174:1-6. Finally, "patients were provided with ketone monitors for free in the clinical trials, but they are expensive to purchase, and there is no guarantee patients would perform ketone monitoring in the real world. To our knowledge, the sponsor is not proposing to distribute ketone monitoring supplies with the drug product." *Id.* 174:12-18.

120. In addition, the FDA highlighted that while Sanofi had focused on the inTandem1 and inTandem 2 studies to show reductions in incidences of severe hypoglycemia, "the trend went ***in the opposite direction*** for [inTandem3]." *Id.* 170:17-20. In sum, "there was ***no consistent trend for hypoglycemia*** across the three phase 3 studies." *Id.* 170:20-22.

121. Sanofi admitted that even that its attempts to address the greater incidence of DKA during the trial had no effect, telling the Committee members that "there's no difference in the rate before and after . . . the rate continued increase throughout the trial." *Id.* 288:22-289:4, 290:5-9.

122. Members of the Advisory Committee also severely criticized sotagliflozin during the meeting, exposing Defendants' false and misleading statements about the drug's performance in the Phase 3 Trials. One committee member stated that ***"[w]e have small reductions in hemoglobin A1C***, ***small reductions in weight*** in a population where that's not a crisis, and we have ***no data to suggest that . . . patients feel better*** on this drug." *Id.* 295:9-15. Another member noted that "I think there is some effect. ***I don't think that it's a huge effect***." *Id.* 300:3-4. A third member stated that "it's not just that there is more DKA; ***it's the fact that it is more severe***." *Id.* 308:16-17. A fourth remarked that "it's impossible to understate the concern about DKA . . . ***the absolute increase is really remarkable*** for a condition," *id.* 309:20-310:3, and "it's ***impossible*** to think that it's not going to be worse in the real world," *id.* 310: 8-10.

123. A Committee member also highlighted the potentially misleading structure of the trials, stating that "We only see an instrument that is ***heavily gamed*** towards time in the therapeutic range of the drug." *See id.* 295:16-18.

124. Other members criticized the presentation of certain purported benefits, including that "from what we hear from the sponsor, they're really making a claim that there was positive endpoint of reduced hypoglycemia. ***I don't think we can say that; the study wasn't designed for that***." *Id.* 301:19-302:1. Similarly, another Committee member noted, "[a]lthough some individuals may have had astounding weight losses, the average change would not let this drug be approvable for a reduction of body weight because it's not a 5% reduction in weight, and that decrease is not "***necessarily considered a strong benefit***." *Id.* 307:4-16.

125. The Committee members also criticized Lexicon's purported strategy for addressing DKA. One stated that "I was surprised to see [] ***very little data*** presented from the sponsor, at least right now, about proof that the risk management strategy works." *Id.* 310:15-18.

Another questioned if the plan could really be effective, since "the sponsor really needs to do a very thorough job in terms of not just sending letters to people, because ***I get letters all the time and you throw them away***." *Id.* 318:7-10.

126. At the end of the Committee Meeting, the Advisory Committee voted "eight to eight" on the question of whether the overall benefits of sotagliflozin outweighed the risks to support approval, and thus did not find that the benefits of sotagliflozin outweighed the risks and did not recommend sotagliflozin for approval.

127. Each of the Advisory Committee members were given the opportunity after voting to explain the basis for their vote. All eight committee members who voted "no" pointed to the dramatic increase in DKA during the Phase 3 Trials, which Defendants had worked so hard to conceal, as outweighing the benefits of the drug. In addition the "no" voters said that the only benefit Lexicon and Sanofi had demonstrated from sotagliflozin was a "modest reduction[] in HbA1c" and that there was no evidence that the risk mitigation strategy of patient screening and ketone monitoring would have any effect on the risk of DKA. The "no" voters also repeatedly emphasized that the closely controlled setting of the Phase 3 Trials likely understated the risk of DKA. One committee member summed it up by saying, "we didn't get to hear from people who had DKA, and their life might have changed from that potentially life-threatening outcome. ***It's increased eightfold, which I couldn't get over***." Comm. Tr. 373:12–19.

I. The FDA Refuses to Approve of Sotagliflozin, and Sanofi Terminates the Sanofi Agreement

128. Trading in Lexicon's stock had been suspended on Thursday, January 17, the day of the Committee Meeting. When trading resumed on Friday, January 18, 2019, the day after the Advisory Committee announced that it had deadlocked on the question of whether "the benefits of sotagliflozin outweighed the risks to support approval," Lexicon's stock price closed at $5.96 per

share, a decline of roughly 23%, and then plummeted to $4.46 on January 25, 2019, as the market digested the implications of the Advisory Committee's deadlock. These declines were attributable to the disclosure of the Advisory Committee's deadlock on sotagliflozin, which revealed that Defendants had been making false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and Defendants' touting of the sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making.

129. The Advisory Committee's deadlocked vote dramatically reduced the likelihood that the FDA would approve sotagliflozin. The day after the Advisory Committee's vote was announced, a Morningstar Analyst informed the market that the FDA was more likely than not to reject the drug, writing "[a]fter a very mixed review of [sotagliflozin's] value in Type 1 diabetes from a U.S. Food and Drug Administration advisory committee on Jan. 17 . . . . ***[w]e reduced our assumed probability of approval for the drug in this indication from 70% to 40% after the meeting***."

130. On March 22, 2019, Lexicon announced that the FDA had issued a "Complete Response Letter" informing the Company that the FDA would not approve sotagliflozin. In a call with analysts and investors after the announcement, Defendants did not provide any insight into why the FDA had refused to approve the drug. Defendants held a call with analysts and investors later that day on March 22, 2019, but refused to identify the reasons why the FDA had rejected the drug.

131. That day, industry observers noted that "given repeated chances to characterize the issues the FDA has — and the $60 million question on whether regulators are demanding more data or posed challenges that can be dealt with in the near-term — [Defendant] Coats repeatedly

batted back the queries without answering them." Carroll, J., *FDA Snubs Sanofi, Lexicon on their Pitch for SGLT1/2 Diabetes Drug Sotagliflozin, Companies Mum on What Went Wrong*, Endpoints News, Mar. 22, 2019, https://endpts.com/fda-snubs-sanofi-lexicon-on-their-pitch-for-sglt1-2-diabetes-drug-sotagliflozin-companies-mum-on-what-went-wrong/. The article went on note that "[t]hat does not bode well for the company or any prospects it may have in the US market, as companies are routinely anxious to seize on short cuts to CRLs. Lexicon also has hundreds of millions of dollars in milestone money sitting on the table for late-stage regulatory goals and commercial launches."

132. On news of the FDA's CRL, Lexicon's stock price fell $1.74 per share, or 21.9%, to close at $6.20 per share on March 22, 2019, before falling further to $5.26 per share on March 28, 2019, as the market digested the implications of the CRL.

133. The Advisory Committee's deadlock, which led to the FDA's decision to deny approval of the drug, created a predicament for Sanofi, which had made an investment of hundreds of millions of dollars in sotagliflozin. The real commercial potential for sotagliflozin was in the T1d market, where it would be the first SGLT-2 inhibitor approved for treatment of T1d. The commercial potential of sotagliflozin for T2d, which Sanofi still needed to seek FDA approval for, however, was considerably lower because, if approved, the drug would enter a market place where a number of SGLT-2 inhibitors had been approved *since 2013*, and much cheaper generic versions of those drugs would be entering the market shortly.

134. Sanofi could terminate the agreement if a regulatory body found the risks associated with sotagliflozin so severe that Lexicon and Sanofi had to stop developing the drug, or if the drug failed to achieve positive results, *i.e.*, certain results at the endpoints of phase 3 clinical trials for T1d or T2d. Sotagliflozin had already achieved the endpoints Defendants had designed to

emphasize the benefits and downplay the risks of the drug in the Phase 3 Trials for T1d. The only way left for Sanofi to terminate its obligations under the agreement was if sotagliflozin failed to reach the endpoints of the phase 3 trials Sanofi was conducting for the drug as a treatment for T2d.

135. On July 26, 2019, Sanofi disclosed that the top-line results for two (out of a total of 10) phase 3 trials it was conducting on the efficacy of sotagliflozin as a treatment for T2d failed to achieve "statically significant reductions" in HbA1c, and that Sanofi was terminating the Sanofi Agreement. Sanofi's termination of the Sanofi Agreement was clearly a result of the Advisory Committee's deadlocked vote, which led to the FDA's decision to reject sotagliflozin. This was a materialization of the risk stemming from Defendants' false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and Defendants' touting of the sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making, which had already led to the Advisory Committee's deadlocked vote at the Committee Meeting and the FDA's decision not to approve sotagliflozin as a T1d treatment.

136. On news of Sanofi's announcement that it was terminating the Sanofi Agreement, Lexicon's stock price fell ***$4.00 per share***, or ***70.3%***, to close at $1.69 per share on July 29, 2019.

MATERIALLY FALSE AND/OR MISLEADING STATEMENTS AND/OR OMISSIONS DURING THE CLASS PERIOD

137. Throughout the Class Period, Lexicon and the Individual Defendants made false and/or misleading statements and/or omissions that (i) minimized the risks of DKA associated with sotagliflozin; (ii) misrepresented that the purported benefits of sotagliflozin would outweigh the risks of DKA; (iii) failed to disclose that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic

drugs; (iv) failed to disclose that Lexicon did not have a meaningful risk management plan for DKA; and (v) as a result, Lexicon's public statements were materially false and misleading at all relevant times. These false and/or misleading statements and/or omissions created a false impression of the likelihood that the Advisory Committee would recommend that the FDA approve sotagliflozin.

A. Defendants Misleadingly Minimized the Serious Risk of DKA Presented By Sotagliflozin

138. As described below, throughout the Class Period Defendants minimized risks of DKA associated with sotagliflozin by downplaying the incidences of the life threatening condition and by failing to disclose that patients taking sotagliflozin in the Phase 3 Trials had experienced an ***eightfold increase*** in the incidence of DKA, that those incidences of DKA were ***severe***, that steps taken to address the incidence of DKA ***did not affect the incidence of DKA***, that incidences of DKA in the Phase 3 Trials were difficult to identify, and that the incidence of DKA was likely ***suppressed by the clinical setting*** of the Phase 3 Trials.

139. For example, the 2015 10-K, which was signed by the Individual Defendants, stated that phase 2 testing of sotagliflozin had shown that the drug "was well tolerated with no discontinuations of study medication due to adverse events." This disclosure was misleading because it suggested to investors that whether clinical trial subjects stopped taking sotagliflozin was the proper way to measure the risks associated with the drug, when, in fact, the eightfold increase in incidences of DKA during the Phase 3 Trials would matter most to the Advisory Committee and the FDA.

140. On August 4, 2016, Lexicon held an earnings call with investors and analysts to report the Company's earnings for the second quarter of 2016. On that call, Defendant Lapuerta told investors that, "one of the things I encourage you to look at is not just the DKA, but take the

DKA into context with other events like A1c reduction and incidence of severe hypoglycemia, and mild-to-moderate hypoglycemia . . . because of that, it's difficult to provide an exact range for one event, when there are three others that need to be taken into account." Lapuerta's statement was misleading because it suggested to investors that the incidence of DKA was not important, when, in fact, the eightfold increase in incidences of DKA during the Phase 3 Trials would matter most to the Advisory Committee and the FDA.

141. On September 9, 2016, Lexicon issued a press release disclosing that the "[t]he number of patients with DKA events during the [inTandem1 Phase 3 Trial's] 24-week treatment period was 0 (0.0%), 3 (1.1%), and 8 (3.1%) in the placebo, 200mg and 400mg dose arms." The press release also quoted the Steering Committee Chairperson as saying that "[s]otagliflozin demonstrated compelling, significant and clinically meaningful A1C reduction with no increase in severe hypoglycemia and ***a slight risk of DKA***." In a conference call with investors and analysts on the same day to report the same inTandem1 results, Defendant Lapuerta also said that "***It was important to show a low incidence of DKA*** and we felt the mechanism by limiting urinary glucose excretion by enhancing GLP-1 with SGLT1 inhibition in sotagliflozin would limit DKA. We were satisfied to see only ***a slight incidence*** of DKA at 1% to 3%." These disclosures were misleading because they downplayed the incidence of DKA while failing to disclose that the incidences of DKA that patients were experiencing were severe, unaffected by the steps taken to reduce the occurrence of DKA, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

142. On December 21, 2016, Lexicon issued a press release that, among other things, disclosed that "the number of patients with DKA events during the 24-week treatment period [of the inTandem2 Phase 3 Trial] was none (0.0%), one (0.4%), and three (1.1%) in the placebo,

200mg and 400mg dose arms, respectively." The release went on to describe sotagliflozin as having "***a favorable overall safety profile*** in the study, including rates of severe hypoglycemia similar to placebo and ***low overall rates of diabetic ketoacidosis***." The December 2016 Release went on to state that "[t]he inTandem2 study demonstrated a ***compelling safety and efficacy profile*** for sotagliflozin in adults living with type 1 diabetes." These disclosures were misleading because they suggested that the sotagliflozin was safe and effective even though in reality sotagliflozin was associated with an increase in incidences of DKA that were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

143. In the 2016 10-K, the Company reported that data for the inTandem1 Phase 3 Trial showed that "The number of patients with DKA events during the 24-week treatment period was 0 (0.0%), 3 (1.1%) and 8 (3.1%) in the placebo, 200mg and 400mg dose arms, respectively." The 2016 10-K also reported that data for the inTandem2 Phase3 Trial showed that "The number of patients with DKA events during the 24-week treatment period was 0 (0.0%), 1 (0.4%) and 3 (1.1%) in the placebo, 200mg and 400mg dose arms, respectively. We are presently completing the 28-week extension portion of the study." These disclosures were misleading because they failed to disclose that the incidences of DKA were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

144. At a January 11, 2017 presentation at the 2017 JP Morgan Healthcare Conference, Defendant Coats summarized the initial results of the inTandem1 and inTandem2 trials. He also told attendees that "you see [an] ***overall low rate of DKA*** in both clinical trials. In fact, in the European trial, you saw a lower rate of DKA in the sotagliflozin arm. However, ***what's most***

important here to us as well is there was very little discontinuation relative to DKA." These disclosures were misleading because they suggested to investors that whether clinical trial subjects stopped taking sotagliflozin was the proper way to measure the risks associated with the drug, when, in fact, the eightfold increase in incidences of DKA during the Phase 3 Trials would matter most to the Advisory Committee and the FDA. These disclosures were also misleading because they failed to disclose that the incidences of DKA were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

145. On May 11, 2017, Lexicon issued a press release disclosing that, in the inTandem1 Phase 3 clinical trial of sotagliflozin, "[t]he rate of diabetic ketoacidosis (DKA) during the 28-week extension period was slightly higher than the rate seen in the initial 24-week treatment period for placebo (one patient, 0.4%) and the 200 mg dose arm (6, 2.5%) and lower for the 400 mg dose arm (3, 1.3%)." The press release also disclosed that "[t]he number of patients with DKA events during the full 52 weeks of treatment was 1 (0.4%), 9 (3.4%), and 11 (4.2%) in the placebo, 200 mg and 400 mg dose arms, respectively." These disclosures were misleading because they did not explain that the results showed a ***greater than eightfold increase*** in incidences of DKA that were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

146. On September 13, 2017, Lexicon issued a press release disclosing results from the inTandem3 trial that stated that "Sotagliflozin demonstrated a ***generally well tolerated safety profile*** during a 24-week treatment period," and that "[t]here was a higher rate of DKA during the 24-week treatment period for sotagliflozin (3.0%) than placebo (0.6%)." This disclosure was false and misleading because it failed to disclose that the increase in DKA seen in all Phase 3 Trials,

which were essentially completed, reflected to an overall eightfold increase in DKA across all three Phase 3 Trials. In addition, the disclosure was misleading because it failed to disclose that the incidences of DKA were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

147. In a November 8, 2017 presentation to investors and analysts disclosing Lexicon's financial performance for the third quarter of 2017, Defendant Coats presented a slide stating that Lexicon had a "Market Advantage" over competitors in the T1d market because the Phase 3 Trials used a "[p]ragmatic study design reflecting real-world setting." This statement was outrageously false and misleading, since not only did the tightly controlled clinical trial setting *not* reflect conditions in the real world, as pointed out by multiple Advisory Committee members, but the Phase 3 Trials had been designed specifically to ***conceal*** the risk of DKA and had ***understated*** the incidence of DKA that was likely to occur in the real world.

148. In the 2017 10-K, which was filed on March 1, 2018 and signed by the Individual Defendants, the Company reported that data for the inTandem1 Phase 3 Trial showed that "[t]he number of patients with positively adjudicated DKA events during the full 52-week treatment period was 1 (0.4%), 9 (3.4%) and 11 (4.2%) in the placebo, 200mg and 400mg dose arms, respectively." The 2017 10-K also reported that data for the inTandem2 Phase 3 Trial showed that "[t]he number of patients with positively adjudicated DKA events during the full 52-week treatment period was 0 (0.0%), 6 (2.3%) and 9 (3.4%) in the placebo, 200mg and 400mg dose arms, respectively." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants. These disclosures were misleading because they failed to disclose a nearly eightfold increase in the incidences of DKA that were

severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

149. In the 2017 10-K, the Company reported that data from the inTandem3 Phase 3 Trial showed that "The number of patients with positively adjudicated DKA events during the 24-week treatment period was 4 (0.6%) and 21 (3.0%) in the placebo and 400mg dose arms, respectively." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants. These disclosures were misleading because they failed to disclose that the incidences of DKA were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

150. Similarly, a June 23, 2018 press release announcing the presentation of the results of the inTandem2 study at an ADA Conference highlighted that "A total of 2.3% of patients on sotagliflozin 200 mg and 3.4% of patients on sotagliflozin 400 mg experienced DKA compared to 0.0% of patients on placebo. Study authors indicate that the DKA risk could potentially be mitigated with patient education and monitoring." The next day, a press release announcing the presentation of the results of the inTandem1 study at the same conference highlighted that "A total of 3.4% of patients on sotagliflozin 200 mg and 4.2% of patients on sotagliflozin 400 mg experienced DKA compared to 0.4% of patients on placebo. Study authors indicate that the DKA risk could potentially be mitigated with patient education and monitoring." These disclosures were misleading because they did not explain that the results showed a ***greater than eightfold increase*** in incidences of DKA that were severe, difficult to identify and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial. These disclosures were also

materially misleading because they failed to disclose that the patient education and monitoring that occurred during the Phase 3 Trials had no effect on the incidence of DKA.

151. In a January 2019 presentation at the JP Morgan Healthcare Conference, Defendant Coats included a slide informing attendees that the Phase 3 Trials showed "Safety data shows manageable incremental DKA risk with less hypoglycemia." This disclosure was misleading because it failed to disclose that the incidences of DKA represented an eightfold increase in DKA over placebo, and were severe, unaffected by the steps taken to reduce their occurrence, difficult to identify, and likely understated as a result of the fact that they were occurring in a tightly controlled clinical trial.

152. As set forth above, the statements in paragraphs 138–151 minimized risks of DKA associated with sotagliflozin by downplaying the incidences of the life threatening condition and by failing to disclose that patients taking sotagliflozin in the Phase 3 Trials had experienced an ***eightfold increase*** in the incidence of DKA, that those incidences of DKA were ***notably severe***, that steps taken to address the incidence of DKA ***did not affect the incidence of DKA***, that incidences of DKA in the Phase 3 Trials were difficult to identify, and that the incidence of DKA was likely ***suppressed by the clinical setting*** of the Phase 3 Trials.

B. Defendants Failed to Disclose That the FDA Had Warned Them Against Using the "Composite Endpoint" in the Phase 3 Trials

153. To obtain results in the Phase 3 Trials that emphasized the purported benefits of sotagliflozin and minimized the risk of DKA, Defendants designed a "composite endpoint" as the secondary endpoint in the inTandem1 and inTandem2 trials and the primary endpoint for the inTandem3 trial. The composite endpoint measured the "*proportion* of patients who achieved an A1c of less than 7% without an episode of severe hypoglycemia or DKA." By reporting the amount of patients who achieved an HbA1c level below 7% without an episode of severe

hypoglycemia or DKA, however, the composite endpoint reported the incidence of a catastrophic, life-threatening condition in the context of how many *more* patients were benefitting from the drug.

154. Unbeknownst to investors, "[d]uring presubmission ***meetings*** with the sponsor, the FDA expressed concern about the utility of the composite endpoint and ***whether it would be adequate to characterize the overall benefit-risk***" of sotagliflozin. Comm. Tr. 118:15–19. As is the general practice in clinical testing of proposed medications, the FDA met with Defendants prior to the start of the Phase 3 Trials in 2015 to discuss the content of those trials. Moreover, the FDA also met with Defendants in the lead-up to the submission of the sotagliflozin NDA in March 2018. Thus, as early as 2015, and in any event by March 2018, *at the latest*, Defendants had *actual knowledge* that the FDA was not in favor of the composite endpoint used by Lexicon in its Phase 3 Trials, and that the composite endpoint did not "actually assess the net benefit of the product or help inform the overall benefit-risk assessment," Comm. Tr. 126:2–7, 127:14–18, and thus that the Advisory Committee was unlikely to vote that the benefits of sotagliflozin outweighed the risks and the FDA was unlikely to approve the drug. While Defendants repeatedly touted to investors throughout the Class Period that the Phase 3 Trials had achieved the composite endpoint, Defendants *never* disclosed the FDA's concerns to investors.

155. For example, a May 11, 2017 press release reporting additional positive data from the inTandem1 trial disclosed that "the outcome on every secondary endpoint favored sotagliflozin over placebo," including "***the proportion of patients achieving A1C <7.0% with no episode of severe hypoglycemia or diabetic ketoacidosis***." The press release also specifically quoted Defendant Coats as saying "we look forward to the outcome of inTandem3, with its 'net benefit' primary efficacy endpoint that measures the proportion of patients achieving an A1C of less than

7% without a severe hypoglycemia or DKA event. ***We saw favorable results on the same endpoint in inTandem1 and inTandem2***."

156. A June 9, 2017 press release reporting top-line results from the inTandem3 study informed investors that the trial had "demonstrating the superiority of sotagliflozin 400 mg compared to placebo in the proportion of patients with A1C <7.0% at Week 24 and no episode of severe hypoglycemia and no episode of diabetic ketoacidosis (DKA) after randomization." Later in the release, Defendant Coats boasted that "Sotagliflozin is the first-ever oral anti-diabetic drug candidate to have achieved success in now three consecutive Phase 3 clinical trials in this population."

157. In an August 15, 2017 press release reporting purported reductions in HbA1c rates over the full 52 weeks of the inTandem2 trial and improvements in the "proportion of patients with A1C < 7.0% at Week 24 with no episode of severe hypoglycemia and no episode of" DKA, Defendant Lapuerta stated that "InTandem2 is the second pivotal study to demonstrate sotagliflozin's ability to durably improve both A1C and other key measures of health such as body weight and blood pressure in patients with type 1 diabetes. Today's results ***underscore sotagliflozin's benefit/risk profile*** and highlight its differentiated profile in the type 1 diabetes landscape."

158. In a September 13, 2017 press release reporting results from the inTandem3 trial, Lexicon claimed that the study "demonstrate[ed] the superiority of sotagliflozin 400 mg compared to placebo in the proportion of patients with A1C <7.0% at Week 24 and no episode of severe hypoglycemia and no episode of DKA after randomization."

159. The 2017 10-K stated that there were "statistically significant improvements . . . in the percentage of patients achieving A1C levels of less than 7% without any severe hypoglycemia

or DKA events." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants.

160. Press releases on June 23, 2018 and June 24, 2018, describing presentations of the results from the inTandem 1 and inTandem2 trials to an ADA conference stated that "sotagliflozin, in combination with insulin, significantly reduced A1C, weight and total daily insulin dose," and that "more patients taking sotagliflozin 200 mg or 400 mg in combination with optimized insulin achieved, with statistical significance, the combined goal of an average blood sugar level below the ADA-recommended target without severe hypoglycemia and without diabetic ketoacidosis (DKA), also referred to as net clinical benefit."

161. As set forth in ¶¶ 153–160 above, these statements were false and misleading because Defendants had failed to disclose that (i) they had had devised the composite endpoint to highlight the benefits of sotagliflozin while concealing the risks of DKA, (ii) the FDA had expressed concerns that the composite endpoint about the endpoint multiple times, and (iii) that the composite endpoint "does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment." Comm. Tr. 126:2–7, 127:14–18:

C. Defendants Misrepresented the Benefits of Sotagliflozin to Suggest that Those Benefits Would Outweigh the Risks of DKA

162. Defendants knew that at the end of the Advisory Committee Meeting, the Advisory Committee would vote as to whether "the available data suggest that the benefits outweigh the risks and support approval of sotagliflozin." Throughout the Class Period, Defendants engaged in a campaign to misrepresent the benefits of sotagliflozin for the purposes of telling investors, the Advisory Committee, and ultimately the FDA that the purported benefits of sotagliflozin outweighed the risks. Defendants misrepresented the benefits of sotagliflozin by (i) structuring the Phase 3 Trials to misleadingly emphasize reductions in HbA1c levels and downplay incidences

of DKA, (ii) touting decreases in HbA1c levels knowing that those levels would not necessarily be meaningful, (iii) touting weight reductions without disclosing that those reductions were under 5% of the patient's body weight and thus not clinically significant, and (iv) downplaying the incidences of DKA.

163. For example, the 2015 10-K stated that phase 2 testing of sotagliflozin had shown "***statistically significant benefits*** in the primary and multiple secondary endpoints . . . . [and] a ***significant improvement*** in glycemic control, with a mean A1C reduction of 0.55% in the Sotagliflozin-treated group compared to a reduction of 0.06% in the placebo-treated group (p=0.002). . . .***Sotagliflozin was well tolerated with no discontinuations of study medication due to adverse events.***"

164. In the 2016 10-K, the Company reported that data for the inTandem1 Phase 3 Trial showed that "patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.43% for the 200mg dose (p<0.001) and 0.49% for the 400mg dose (p<0.001), as compared to a reduction of 0.08% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint." The 2016 10-k also reported that data for the inTandem2 Phase 3 Trial showed that "patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.39% for the 200mg dose (p<0.001) and 0.37% for the 400mg dose (p<0.001), as compared to a reduction of 0.03% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants.

165. On September 9, 2016, Lexicon issued a press release disclosing that the inTandem1 Phase 3 clinical trial of sotagliflozin had "met its primary endpoint, ***showing a statistically significant reduction in A1C at 24 weeks in patients with type 1 diabetes***." The press

release stated that patients treated with sotagliflozin "had a mean A1C reduction from baseline of 0.43%" on a 200 mg dose and "a reduction of 0.49%" on a 400 mg dose after 24 weeks of treatment." The press release continued, "[t]his ***statistically significant and clinically meaningful improvement in A1C*** for both doses of sotagliflozin was achieved without an increase in severe hypoglycemia, one of the most prevalent serious health challenges in type 1 diabetes, which was seen less frequently in both treatment arms than placebo."

166. On December 21, 2016, Lexicon issued a press release disclosing that the inTandem2 Phase 3 clinical trial of sotagliflozin had "met its primary endpoint, ***showing a statistically significant reduction in A1C at 24 weeks in patients with type 1 diabetes***." The press release stated that patients treated with sotagliflozin "had mean A1C reductions from baseline of 0.39%" on a 200 mg dose and "a reduction of 0.37%" on a 400 mg dose after 24 weeks of treatment." The press release continued, "[t]his ***statistically significant and clinically meaningful improvement in A1C*** for both doses of sotagliflozin with ***a favorable overall safety profile*** in the study, including rates of severe hypoglycemia similar to placebo and ***low overall rates of diabetic ketoacidosis (DKA)***." These disclosures were materially misleading because they failed to disclose that the mean HbA1c were not *meaningful* and thus did not outweigh the serious risk of severe DKA, the incidence of which had increased eightfold over placebo in the Phase 3 Trials.

167. On March 6, 2017, Lexicon filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the fiscal year ended December 31, 2016 (the "2016 10-K"). The 2016 10-K touted the positive results of Lexicon's Phase 3 clinical trials for Sotagliflozin, stating that the Company had "reported positive top-line primary efficacy endpoint data from two pivotal Phase 3 clinical trials of Sotagliflozin in type 1 diabetes patients[.]" These disclosures were materially misleading because they failed to disclose that the mean HbA1c

were not *meaningful* and thus did not outweigh the serious risk of severe DKA, the incidence of which had increased eightfold over placebo in the Phase 3 Trials.

168. In the 2017 10-K, the Company reported that data from the inTandem1 Phase 3 Trial showed that "patients treated with sotagliflozin experienced statistically significant reductions in A1C from baseline of 0.43% for the 200mg dose ($p<0.001$) and 0.48% for the 400mg dose ($p<0.001$), as compared to a reduction of 0.07% on placebo after 24 weeks of treatment, meeting the study's primary efficacy endpoint." 2017 The 10-K also stated that "[t]he A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses." The 2017 10-K also stated that there were "statistically significant improvements . . . in the percentage of patients achieving A1C levels of less than 7% without any severe hypoglycemia or DKA events." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants. These disclosures were materially misleading because they failed to disclose that the mean decreases in HbA1c were not *meaningful* and thus did not outweigh the serious risk of severe DKA, the incidence of which had increased eightfold over placebo in the Phase 3 Trials. These statements were also false and misleading because Defendants failed to disclose that the composite endpoint emphasized the modest benefits of sotagliflozin while concealing the risks of DKA.

169. In a press release announcing top-line results for the inTandem2 Phase 3 Trial dated December 21, 2016, the Company disclosed that "patients treated with sotagliflozin had mean A1C reductions from baseline of 0.39% on 200mg once daily sotagliflozin dose ($p<0.001$) and 0.37% on 400mg once daily sotagliflozin dose ($p<0.001$) as compared to a reduction of 0.03% on placebo after 24 weeks of treatment." These disclosures were materially misleading because they failed to disclose that the mean decreases in HbA1c were not *meaningful* and thus did not outweigh the

serious risk of severe DKA, the incidence of which had increased eightfold over placebo in the Phase 3 Trials.

170. In the 2017 10-K, the Company reported that data from the inTandem2 Phase 3 Trial repeated the disclosure of A1C reductions from the December 21 Press Release. The 2017 10-K also stated that "[t]he A1C benefit achieved with sotagliflozin was sustained with statistically significant results over the full 52-week duration of the study for both the 200mg and 400mg doses." The 2017 10-K also stated that "[s]tatistically significant improvements in all secondary efficacy endpoints were observed in both the 200mg and 400mg dose arms compared to placebo," *i.e.*, in the percentage of patients achieving A1C levels of less than 7% without any severe hypoglycemia or DKA events. These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants. These disclosures were materially misleading because they failed to disclose that the mean decreases HbA1c were not *meaningful* and thus did not outweigh the serious risk of severe DKA, the incidence of which had increased eightfold over placebo in the Phase 3 Trials. These statements were also false and misleading because Defendants failed to disclose that the composite endpoint emphasized the modest benefits of sotagliflozin while concealing the risks of DKA.

171. In the 2017 10-K, the Company reported that data from the inTandem3 Phase 3 Trial showed "statistically significant superiority of sotagliflozin (28.6%) compared to placebo (15.2%) in the proportion of patients achieving A1C levels of less than 7% without experiencing a severe hypoglycemic or DKA event ($p<0.001$), meeting the study's primary endpoint." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants. These statements were false and misleading because Defendants failed

to disclose that the "net benefit" composite endpoint emphasized the modest benefits of sotagliflozin while concealing the risks of DKA.

172. Press releases on June 23, 2018 and June 24, 2018, describing presentations of the results from the inTandem 1 and inTandem2 trials to an ADA conference stated that "sotagliflozin, in combination with insulin, ***significantly reduced A1C***, ***weight*** and total daily insulin dose."

173. As set forth in paragraphs 162–172 above, Defendants misrepresented the benefits of sotagliflozin throughout the Class Period by (i) structuring the Phase 3 Trials to misleadingly emphasize reductions in HbA1c levels and downplay incidences of DKA, (ii) touting decreases in HbA1c levels knowing that those levels would not necessarily be meaningful for patients with starting HbA1c levels over 8%, (iii) touting weight reductions without disclosing that those reductions were under 5% of the patient's body weight and thus not clinically significant, and (iv) downplaying the incidences of DKA.

D. Defendants' Statements Concerning Sotagliflozin's Effects on "Time Spent in Glucose Range" and "Glycemic Variability" Were Materially Misleading

174. Throughout the Class Period, Defendants touted Sotagliflozin's performance in Phase 2 and Phase 3 clinical trials by emphasizing how the drug performed in relation to certain "glucose-based endpoints," including Time-in-Range and Glycemic Variability. As the FDA wrote in its briefing materials, however, "[w]hile these endpoints [*i.e.*, Time-in-Range and Glycemic Variability] are valued by patients and may relate to at least short-term improvements in quality of life and treatment satisfaction, these ***do not have an established relationship with long-term macrovascular and microvascular complications*** and ***have not been validated for use in regulatory decision making for antidiabetic drugs***." In other words, sotagliflozin's performance with regard to Time-in-Range and Glycemic Variability was *entirely irrelevant* as to

whether the Advisory Committee recommended that the FDA approve sotagliflozin or whether the FDA ultimately approved the drug.

175. Although Defendants knew, or were reckless in not knowing, that Time-in-Range and Glycemic Variability would not be used in regulatory decision making for sotagliflozin, they nevertheless touted sotagliflozin's performance with reference to these metrics

176. For example, The 2015 10-K stated that phase 2 trials not only showed that sotagliflozin provided patients with "statistically significant benefits," but also that:

> [t]hese observations were also accompanied by significant improvement in the ***time spent in a glucose range*** of 70-180 mg/dl, a significant reduction in ***time in hyperglycemic range*** (>180 mg/dl) and no increase ***in time in hypoglycemic range*** (<70mg/dl). Multiple measures also indicated that patients treated with Sotagliflozin experienced ***reduced variability*** in blood glucose levels.

177. Similarly, on an August 4, 2016 earnings call with analysts and investors to report Lexicon's earnings for the second quarter of 2016, Defendant Lapuerta suggested to investors that the Time-in-Range and Glycemic Variability measures outweighed – or at least counter-balanced – incidences of DKA, even though the measures were irrelevant to whether the drug would be recommended or approved. Lapuerta said, "we do think . . . that there is an acceptable range that you can have some DKA, but still have proposition that's very favorable to patients. And I think, one of the most important propositions that we are looking to is to see whether or not we can improve time and range, which for patients would mean ultimately a lower risk of hypoglycemia and that's a big issue to patients."

178. In September 8, 2017 press release updating investors on data from the inTandem1 and inTandem2 trials, Defendants stated that "patients treated with 200 mg and 400 mg doses of sotagliflozin spent a 5.4% and 11.7% greater proportion of the day, respectively, ***in the target glucose range*** of 70-180 mg/dL than those taking placebo, which translated into an additional 1.3 hours and 2.8 hours in a 24-hour period, respectively." These statements were repeated in a

presentation to investors on November 8, 2017 that disclosed Lexicon's financial performance for the third quarter of 2017, as well as in a presentation by Defendant Coats to attendees at a September 5, 2018 healthcare conference sponsored by Wells Fargo.

179. The 2017 10-K, which was signed the by the Individual Defendants, also told investors that Lexicon had "pooled continuous glucose monitoring, or CGM, data in September 2017 from the inTandem1 and inTandem2 clinical trials," which showed that the "percentage of time during the initial 24-week treatment period spent inside the target range for CGM glucose (70-180 mg/dL) increased" for patients on sotagliflozin." These representations were repeated in the 2018 10-K, which was filed on March 15, 2019 and signed by the Individual Defendants.

180. In a June 23, 2018 press release announcing the presentation of the results of the inTandem2 study at an ADA Conference highlighted for investors that "[i]mprovements in certain elements of glycemic control beyond A1C were also observed [in inTandem2], including fasting plasma glucose (FPG) and ***glycemic variability***."

181. Finally, a presentation by Defendant Coats to attendees at the January 9, 2019 JP Morgan Healthcare Conference included a slight that stated that the Phase 3 Trials showed that sotagliflozin increased patients' Time-in-Range and decreased a patients' Glycemic Variability.

182. The statements referenced in ¶¶ 174–181 were materially false and misleading because while Defendants were touting the performance of sotagliflozin with regards to Time-in-Range and Glycemic Variability, Defendants failed to disclose that those measures did not have an established relationship with long-term macrovascular and microvascular complications and were not been validated for use in regulatory decision making, and thus would have no impact on whether the Advisory Committee recommended sotagliflozin or the FDA ultimately approved the drug.

E. Defendants Failed to Disclose That They Had Not Prepared a Meaningful Risk Management Program for Sotagliflozin

183. In addition to downplaying the risks of DKA associated with sotagliflozin, Defendants also made materially false and/or misleading statements throughout the Class Period by telling investors that they were developing or had developed an effective risk management program to address DKA, but failing to disclose that they had utterly failed to create any semblance of such a plan. These misrepresentations were material because Defendants knew that they needed to propose a risk management program given the increase in incidence of DKA and the FDA's prior statements of concern about DKA associated with SGLT-2 inhibitors, like sotagliflozin.

184. In their briefing materials and presentation to the Advisory Committee during the Advisory Committee meeting, Defendants told Advisory Committee members that the risks of DKA could be mitigated by essentially sending letters to physicians recommending that physicians carefully screen out potential sotagliflozin patients who might be at a higher risk of DKA, as well as providing physical and online literature to patients asking them to be alert for symptoms of DKA, to check their ketone levels and to contact their healthcare providers if their ketone were positive or if their condition did not improve.

185. The Advisory Committee members *excoriated* Defendants' proposed "plan," emphasizing, among other things, that physicians and patients routinely ignore literature provided by pharmaceutical companies; Defendants had not suggested how patients would obtain ketone testing kits, which are expensive, or how follow-ups would be conducted to ensure that patients were actually checking their ketone levels; patients in the Phase 3 studies had experienced DKA before the typical symptoms alerting them of an attack had manifested themselves; and Defendants had not provided *any* evidence suggesting that patients would actually check their ketone levels regularly as instructed.

186. In addition, Defendants had actual notice that their risk management "plan" was woefully inadequate and likely ineffectual because Defendants had instructed the investigators conducting the trials and patients participating in the trials to be alert for DKA when taking sotagliflozin and provided patients with ketone test kits and the incidence of DKA ***was entirely unaffected by these measures***.

187. Throughout the Class Period, Defendants repeatedly represented to investors that they understood the need for a risk management plan and were in fact developing such a plan, but failed to disclose that no such plan existed. For example, at a presentation to investors at the 2017 JP Morgan Healthcare Conference on January 11, 2017, Defendant Coats told investors that the Phase 3 Trials would "put[] us in the position both to be able to show statistically significance relative to insulin as an adjunct, ***as well as be able to answer the question, how do you manage a patient who may be in the situation where they have DKA and/or severe hyperglycemic events***." Later in the same presentation, Defendant Coats said, "we will be in a position to be able ***to show how to manage***, if not to prevent, DKA. That would be the responsibility that we have going forward."

188. Similarly, in a November 8, 2017 presentation disclosing Lexicon's third quarter 2017 financial results, Defendant Coats showed a slide stating that the Phase 3 Trials "have demonstrated manageable incremental DKA risk over placebo ***that can be mitigated with appropriate care instructions and monitoring***." Later in the same presentation, another slide claimed that "***DKA is manageable with appropriate care instructions***."

189. A June 23, 2018 press release announcing the presentation of the results of the inTandem2 study at an ADA Conference highlighted that, "A total of 2.3% of patients on sotagliflozin 200 mg and 3.4% of patients on sotagliflozin 400 mg experienced DKA compared to

0.0% of patients on placebo. Study authors indicate that the DKA risk could potentially be mitigated ***with patient education and monitoring***." The next day, a press release announcing the presentation of the results of the inTandem1 study at the same conference also highlighted that "Study authors indicate that the DKA risk could potentially be mitigated ***with patient education and monitoring***."

190. Defendant Coats also made a presentation at the January 9, 2019 JP Morgan Healthcare Conference, where he told attendees that, "[w]e think the key to managing the risk of DKA is certainly around education and awareness, and ***we're starting to see education suggestions coming from clinical associations on the use of SGLTs for type 1 [diabetes]***." In the PowerPoint presentation provided by Defendant Coats to attendees, Defendant Coats including a slide referencing statements and publications describing strategies for DKA risk management in SGLT-2 inhibitors, suggesting to investors that Lexicon was using these strategies to develop its risk management program for sotagliflozin.

191. Defendants' statements in paragraphs 183–190 above represented to investors that Defendants understood the need for a thorough, detailed and demonstrably effective risk management plan and were in fact developing such a plan. These statements were materially misleading, however, because they failed to disclose to investors that no such plan existed.

F. The Individual Defendants' Signed Certifications Attached to Lexicon's 10-Ks and 10-Qs During the Class Period Were False and Misleading

192. During the Class Period Lexicon filed quarterly and annual reports with the SEC on Form 10-K. Under the securities laws, these filings were required to be accompanied by signed certifications attesting to, among other things, that the quarterly and annual reports comply with the Securities Exchange Act of 1934 and that the information contained in those reports "fairly presents, in all material respects, the financial condition and results of operations of Lexicon." The

Individual Defendants signed certifications for each quarterly and annual report filed by Lexicon during the class period.

193. As described below, the certifications signed by the Individual Defendants were materially false and misleading because the 10-Ks associated with each certification contained materially false and/or misleading statements and/or omissions (i) minimizing the risks of DKA associated with sotagliflozin; (ii) misrepresenting that the purported benefits of sotagliflozin would outweigh the risks of DKA; (iii) failing to disclose that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs; (iv) failing to disclose that Lexicon did not have a meaningful risk management plan for DKA.

194. For example, appended as exhibits to the 2015 10-K were signed certifications by the Individual Defendants pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), "certify[ing] that: 1. Lexicon's [2015 10-K] fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, and 2. The information contained in the [2015 10-K] fairly presents, in all material respects, the financial condition and results of operations of Lexicon."

195. Appended as exhibits to the 2016 10-K were signed SOX certifications by the Individual Defendants "certify[ing] that: 1. Lexicon's [2016 10-K] fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, and 2. The information contained in the [2016 10-K] fairly presents, in all material respects, the financial condition and results of operations of Lexicon."

196. Appended as exhibits to the 2017 10-K were signed SOX certifications by the Individual Defendants "certify[ing] that: 1. Lexicon's [2017 10-K] fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, and 2. The

information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of Lexicon."

197. Appended as exhibits to the 2018 10-K were signed SOX certifications by the Individual Defendants "certify[ing] that: 1. Lexicon's [2018 10-K] fully complies with the requirements of section 13(a) or section 15(d) of the Securities Exchange Act of 1934, and 2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of Lexicon."

198. The statements referenced in ¶¶ 192–198 were materially false and misleading because the 10-Ks associated with each certification referenced in those paragraphs contained materially false and/or misleading statements and/or omissions (i) minimizing the risks of DKA associated with sotagliflozin; (ii) misrepresenting that the purported benefits of sotagliflozin would outweigh the risks of DKA; (iii) failing to disclose that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs; (iv) failing to disclose that Lexicon did not have a meaningful risk management plan for DKA.

THE TRUTH BEGINS TO EMERGE

199. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

200. Throughout the Class Period, the price of Lexicon's securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants' materially false and misleading statements and omissions identified herein.

201. The price of Lexicon's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged hereinto have been concealed from the market, and/or the effects thereof materialized and/or were revealed, causing

investors' losses. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

202. On January 17, 2019, the Advisory Committee met to vote on whether the overall benefits of sotagliflozin outweighed its risks to support approval.

203. The FDA prepared a briefing document for the panel members of the Advisory Committee, dated January 17, 2019 (the "Briefing Document"), for the Advisory Committee to consider when voting on Zynquista's benefit versus risk analysis. In the section titled "Safety and Efficacy: Executive Summary and Conclusions," the Briefing Document stated that diabetic ketoacidosis ("DKA") "was the most notable and concerning adverse reaction associated with Sotagliflozin." Specifically, the FDA found the following:

- "Sotagliflozin was associated with an approximately 8-fold increase in DKA risk vs. placebo (95% CI: [3.1, 19.9]). The estimated number needed to harm (NNH) was approximately 26 patient-years of exposure to Sotagliflozin to observe 1 additional DKA event (95% CI: [20.1, 38.5])";
- "Subgroup analyses showed a consistently elevated DKA risk associated with Sotagliflozin, with estimated hazard ratios ranging from 4 to 11, and NNH ranging from 11 to 37";
- "The risk of DKA associated with Sotagliflozin was consistently observed across subgroups";
- "The observed risk of DKA was highest, independently of treatment, in subjects with the following characteristics: prior DKA history, young age, high baseline A1c, and CSII insulin delivery method, i.e. pump use"; and
- "Sensitivity analyses by including pre-DKA and additional FDA-adjudicated DKA events (data not shown in these background materials) did not change the general conclusion."

204. Aside from troubling data concerning the incidence of DKAs, the FDA's Briefing Document also summarized the implications of various serious adverse events ("SAEs") associated with sotagliflozin:

> Overall, there was a greater number of subjects in the Sotagliflozin treatment group that reported treatment-emergent serious adverse events[] (SAEs) in comparison to the placebo group, with a total of 103/1049 subjects (9.8%) in the pooled Sotagliflozin group, and 37/526 subjects (7.0%) in the placebo group. The greatest number of SAEs occurred in the system organ class (SOC) "Metabolism and Nutrition SOC", which occurred in 56/1049 subjects (5.3%) in the pooled Sotagliflozin group, and in 9/526 subjects (1.7%) in the placebo group. The large majority of PTs within this SOC were "diabetic ketoacidosis", which occurred in 45 subjects (4.3%) in the pooled Sotagliflozin group, and 3 subjects (0.6%) in the placebo arm. There was no imbalance in events of hypoglycemia, represented by the PT "hypoglycemia" within the "Metabolism and Nutrition SOC, and "hypoglycemic unconsciousness" within the "Nervous System Disorders SOC", with similar number of events in the three groups. Events of DKA and hypoglycemia are discussed in more detail below.
>
> The next most common SOC was "Infections and Infestations", with a slightly greater number of events occurring in the pooled Sotagliflozin group (1.6%) compared to the placebo group (1.0%). The PTs that occurred with greater frequency in the Sotagliflozin group within this SOC were "pneumonia" and "gastroenteritis". There was no major imbalance in the incidence of SAEs in the remaining SOCs or PTs between treatment groups.

205. In addition, during the course of the Committee Meeting, representatives of the FDA informed the Committee that:

- The FDA had told Defendants prior to Phase 3 Trials commencing, or at the very least prior to the submitting of the new drug application for sotagliflozin, that the "composite endpoint" used in the Phase 3 Trials was likely misleading.

- "***the sponsor-defined net benefit endpoint masked the increased risk of DKA in the sotagliflozin groups and does not actually assess the net benefit of the product or help inform the overall benefit-risk assessment***."

- "The rate of DKA continued to increase for the sotagliflozin group throughout the trial while the rate for placebo remains flat."

206. In addition, during the course of the Committee Meeting, representatives of Sanofi, on behalf of Lexicon, admitted to the Committee that:

- Over 1/3 of the instances of DKA observed in patients taking sotagliflozin was "severe," while none of the incidences on placebo were severe.

- Typical indicators of DKA (increased thirst or urination) were not reliable to detect emerging DKA and thus that patients "have less early signs and symptoms to detect

emerging DKA and must rely on ketosis-related signs and symptoms" including tests for the presence of ketones.

- The methods developed by Defendants to address the greater incidence of DKA during the trial, including adding questions to screening forms to identify potentially at-risk subjects, physician and patient warnings, and the provision of ketone test strips and BHB monitors had had no effect on the incidence of DKA, telling the Committee members that "there's no difference in the rate before and after . . . the rate continued increase throughout the trial."

207. As described in the minutes of the Advisory Committee meeting, various members "questioned the clinical relevance of the modest reduction of hemoglobin A1c (HbA1c) shown with the use of sotagliflozin." Specifically, members of the Advisory Committee stated that they could not vote that the benefits of sotagliflozin outweighed the risks because:

- "We have ***small reductions in hemoglobin A1C***, ***small reductions in weight*** in a population where that's not a crisis, and we have ***no data to suggest that . . . patients feel better on this drug."***
- "It's not just that there is more DKA; ***it's the fact that it is more severe***."
- There was ***no evidence*** the risk mitigation strategy proposed by Lexicon actually worked.
- It's impossible to understate the concern about DKA . . . the absolute increase is really remarkable for a condition," and "it's ***impossible*** to think that it's not going to be worse in the real world."

208. The same day, Lexicon announced that the Advisory Committee had "voted eight to eight on the question of whether the overall benefits of [Lexicon's product] Zynquista (sotagliflozin) outweighed the risks to support approval," stalemating on the issue of whether sotagliflozin's overall benefits outweighed its risks to support approval.

209. On January 18, 2019, analysts began to digest the eight to eight vote by the Advisory Committee and how it impacted the Company's value. For example, in a January 18, 2019 *The Motley Fool* article by Maxx Chatsko ("Chatsko"), titled "Here's Why Lexicon Pharmaceuticals Collapsed Today," Chatsko noted that "an advisory committee of the [FDA] reached a stalemate when deciding whether the benefits of Zynquista outweighed the risks. The

final vote was eight in favor of approval and eight against approval. The impasse means investors have no way of knowing the path forward for the drug candidate[.]" Chatsko also pointed out that "analysts expected the drug candidate . . . to have blockbuster potential" that "might be in doubt now or, at the very least, the timeline has been pushed back."

210. On this news, Lexicon's stock price fell $1.74 per share, or 22.6%, to close at $5.96 per share on January 18, 2019. Then, as the market digested the extent of Defendants' misrepresentations and omissions, Lexicon's share price plummeted over the next several days before hitting bottom at $4.46 on January 25, 2019, a decline of over 42%. These declines were attributable to the disclosure of the Advisory Committee's deadlocked vote on sotagliflozin for approval, which revealed Defendants' false and misleading statements and/or omissions.

LOSS CAUSATION

211. The Committee Meeting was the first time that the market learned of the full extent of the increase in DKA in patients taking sotagliflozin over patients taking placebo; (ii) that the FDA had specifically warned Defendants that the composite endpoint was not reliable and hid the risk of DKA, (iii) that the benefits of sotagliflozin were only modest, (iv) that the Time-in-Range and Glycemic Variability measures touted by Lexicon had not been validated for use in regulatory decision making for antidiabetic drugs, and (v) that Lexicon did not have a meaningful risk management plan for DKA, which was essential to the successful approval of sotagliflozin.

212. Lexicon's stock price closed trading at $7.70 per share on Wednesday, January 16, 2019. Trading in Lexicon's stock was suspended on Thursday, January 17, the day of the Committee Meeting. When trading resumed on Friday, January 18, 2019, the day after the Advisory Committee announced that it had deadlocked on the question of whether "the benefits of sotagliflozin outweighed the risks to support approval" and Defendants misrepresentations and omissions were exposed, Lexicon's stock price closed at $5.96 per share, a decline of roughly

23%. Then, as the market recognized the extent of Defendants' misrepresentations and omissions, Lexicon's share price plummeted over the next several days before hitting bottom at $4.46 on January 25, 2019, a decline of over 42% its closing price on January 16, 2019.

213. These declines were attributable to the disclosure of the Advisory Committee's decision not to recommend sotagliflozin for approval, which revealed that Defendants had been making false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and Defendants' touting of the sotagliflozin's performance with regards to measures that had not been validated by the FDA for use in regulatory decision making.

214. Although the Advisory Committee's deadlocked vote did not *require* the FDA to reject the new drug application for sotagliflozin, it dramatically reduced the likelihood that the drug would be approved. The day after the Advisory Committee's vote was announced, a Morningstar Analyst informed the market that the FDA was more likely than not to reject the drug, writing "[a]fter a very mixed review of [sotagliflozin's] value in Type 1 diabetes from a U.S. Food and Drug Administration advisory committee on Jan. 17 . . . . ***[w]e reduced our assumed probability of approval for the drug in this indication from 70% to 40% after the meeting***." Similarly, a writer for The Motley Fool noted that the Committee's impasse "means ***investors have no way of knowing the path forward*** for the drug candidate," and that the drug's "***blockbuster potential . . . might be in doubt now*** or, at the very least, the timeline has been pushed back."

215. On March 22, 2019, Lexicon announced that the FDA had issued a "Complete Response Letter" informing the Company that the FDA would not approve sotagliflozin. In a call with analysts and investors after the announcement, Defendants did not provide any insight into

why the FDA had refused to approve the drug. On news of the FDA's CRL, Lexicon's stock price fell $1.74 per share, or 21.9%, to close at $6.20 per share on March 22, 2019. Lexicon's stock price continued to fall over the next week as the market digested the FDA's refusal to approve sotagliflozin. The Company's stock price bottomed out on March 28 at $5.26 per share, a total decline of 33.8% from its closing price on March 22, 2019.

216. The Advisory Committee's deadlock, which led to the FDA's decision to deny approval of the drug, severely restricted the commercial potential for sotagliflozin as a T1d treatment because it delayed the release of the drug indefinitely, increased the likelihood that the drug would carry strong safety warnings that could reduce use, and allowed competing SGLT-2 inhibitors that were in development as treatments for T1d time to catch up to sotagliflozin and potentially be the first drugs to market. Indeed, in the wake of the meeting, a JPMorgan analyst highlighted "lingering concerns around what DKA risk/label warnings could mean for commercial uptake" of sotagliflozin. Moreover, CW2 recalled that on a call with the European Association for the Study of Diabetes, participants from Lexicon worked to distinguish sotagliflozin from another similar drug that was being developed by a Lexicon competitor.

217. It also created a predicament for Sanofi, which had made an investment of hundreds of millions of dollars in sotagliflozin, which was now unlikely to be approved by the FDA for T1d in part because of serious health risks. Under the Sanofi Agreement, Sanofi had already paid Lexicon $300 million and was still on the hook for, among other things, continuing to sponsor the application for FDA approval of the drug as a treatment for T1d, commercializing the drug as a treatment for T1d worldwide, and for all clinical development and commercialization of sotagliflozin as a treatment for T2d. The real commercial potential for sotagliflozin was in the T1d market, where it would be the first SGLT-2 inhibitor approved for treatment of T1d. Indeed,

Defendant Coats had boasted to investors that Lexicon estimated that the market for T1d treatments was $5 billion, and a Jefferies analyst had suggested that the drug's revenues could reach $1 billion annually. The commercial potential of sotagliflozin for T2d, however, was considerably lower because, if approved, the drug would enter a market place where a number of SGLT-2 inhibitors had been approved *since 2013*, and much cheaper generic versions of those drugs would be entering the market shortly. As a JPMorgan analyst wrote, "[w]e also, however, continue to see a challenging commercial position for sota in Type 2 as a late-to-market entrant with multiple established agents in the class (so established that we see a limited window within which sota could launch prior to generic entry for other players and likely therapeutic substitution). Similarly, a Morningstar analyst commented that "We see very high uncertainty surrounding the value of Lexicon shares, largely ***due to a tough competitive landscape with SGLT2 inhibitors approved in Type 2 diabetes*** and progressing in Type 1 diabetes."

218. Sanofi needed a way out of the boondoggle that sotagliflozin had turned into in light of the Advisory Committee's deadlock and the FDA's decision not to approve the drug. Under the terms of the Sanofi Agreement, however, Sanofi could only terminate the agreement if a regulatory body found the risks associated with sotagliflozin so severe that it instructed Lexicon and Sanofi to stop developing the drug, or if the drug failed to achieve positive results, *i.e.*, achieve the endpoints of phase 3 clinical trials. Sotagliflozin had already achieved the endpoints Defendants had designed to emphasize the benefits and downplay the risks of the drug in the Phase 3 Trials. The only way left for Sanofi to terminate its obligations under the agreement was if sotagliflozin failed to reach the endpoints of the phase 3 trials Sanofi was conducting for the drug as a treatment for T2d.

219. On July 26, 2019, Sanofi disclosed top-line results for three phase 3 trials testing the efficacy of sotagliflozin as a treatment for T2d in patients (i) already taking the diabetes treatment metformin, (ii) suffering from moderate chronic kidney disease ("CKD"), and (iii) suffering from severe CKD (the "SOTA-CKD4 study"). According to Sanofi, the trial of a *subgroup* of patients suffering from CKD (not the full population of patients in the trial), and the trial of the full population of patients suffering from severe CKD, failed to achieve "statically significant reductions" in HbA1c. Based on these results, Sanofi said, it had provided notice to Lexicon that it was terminating the Sanofi Agreement. Sanofi's decision to terminate the Sanofi Agreement was clearly a result of the Advisory Committee's deadlocked vote, which led to the FDA's decision to reject sotagliflozin.

220. In Lexicon's press release on the same day, Defendant Lapuerta responded on behalf of Lexicon that "Although the SOTA-CKD4 study appears to have narrowly missed statistical significance on A1C, we are very encouraged by the overall results in that study and look forward to Phase III data from the remainder of the core studies from the InSynchrony program later this year." Lexicon also disclosed that it had sent a notice to Sanofi declaring that *Sanofi* was in breach of the Sanofi Agreement. Recognizing that the commercial potential of sotagliflozin was severely restricted as a result of the Advisory Committee's deadlocked vote and the FDA's refusal to approve the drug, Sanofi had seized on slight underperformance in two of the ten phase 3 studies it was conducting to terminate the Sanofi Agreement. This was a materialization of the risk stemming from Defendants' false and misleading statements and/or omissions concerning the risk to patients of DKA, the drug's effectiveness, the FDA's concerns regarding the "composite endpoint" in the Phase 3 Trials and Defendants' touting of the sotagliflozin's performance with regards to measures that had not been validated by the FDA for

use in regulatory decision making, which had already led to the Advisory Committee's deadlocked vote at the Committee Meeting and the FDA's decision not to approve sotagliflozin as a T1d treatment.

221. On news of Sanofi's announcement that it was terminating the Sanofi Agreement, Lexicon's stock price fell ***$4.00 per share***, or ***70.3%***, to close at $1.69 per share on July 29, 2019.

ADDITIONAL SCIENTER ALLEGATIONS

222. As set forth above, Defendants made the misstatements and/or omissions with actual knowledge of their falsity or, at a minimum, recklessly disregarded the facts described in "Substantive Allegations" section above for the following reasons.

(a) Defendants were responsible for all clinical development activities relating to sotagliflozin for T1d and thus knew the truth about the limited benefits and severe risks associated with the drug,

(b) The Company was hemorrhaging money and could not survive without FDA approval of sotagliflozin, and

(c) Defendants structured the endpoints of the Phase 3 Trials of sotagliflozin expressly to mask the incidence and severity of DKA in those Trials.

223. In addition to the above allegations, which on their own create a strong inference of scienter, the Individual Defendants' scienter is also established because the alleged misstatements and omissions at issue here concerned Lexicon's core operations. Indeed, one of the central allegations is that sotagliflozin was essential to the Company's survival. In addition, each annual report on Form 10-K and quarterly report on form 10-Q filed by Lexicon during the Class Period, which was signed by the Individual Defendants and included certifications by the Individual Defendants as to the accuracy of the reports' contents, stated that sotagliflozin was one of Lexicon's "most advanced drug programs" and that the Company was "devoting most of [its] resources to the commercialization or development" of those programs, including sotagliflozin.

224. Moreover, under the terms of the Sanofi Agreement, Lexicon had grated Sanofi the entire rights to commercialize sotagliflozin for T1d and T2d outside of the United States. Thus Lexicon's royalties for sales of sotagliflozin outside of the United States paled in comparison to the royalty the Company was entitled to for sales of sotagliflozin inside the United States. Defendant Coats himself told analysts and investors on a March 1, 2016 conference call that royalties Sanofi would pay Lexicon would "range[] ***from low double-digit percentages to 40% of net sales, specifically in the U.S.*** and for type 1 diabetes." Accordingly, the Individual Defendants knew that for Lexicon to obtain the substantial royalties under the Sanofi Agreement, they could not rely on approval of sotagliflozin outside the United States; it was essential the FDA approve sotagliflozin.

225. Finally, CW3, the former Head of Commercial Operations for Lexicon from August 2016 to March 2018, stated that Defendant Coats's compensation was directly tied to FDA approval of sotagliflozin. Defendant Coats thus was incentivized to fraudulently emphasize the modest benefits of sotagliflozin while concealing the risks of DKA. Defendants Wade and Lapuerta had compensation packages tied to FDA approval of sotagliflozin as well.

NO SAFE HARBOR

226. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and/or there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to

any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of the Company who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

227. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all those who purchased or otherwise acquired Lexicon securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of Lexicon, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

228. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Lexicon securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Lexicon or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

229. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

230. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

231. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(d) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(e) Whether statements made by Defendants to the investing public during the Class Period misrepresented or omitted material facts about the business, operations and management of Lexicon;

(f) Whether the Individual Defendants caused Lexicon to issue false and misleading financial statements during the Class Period;

(g) Whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(h) Whether the prices of Lexicon securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and

(i) Whether the members of the Class have sustained damages and, if so, what is the proper measure of damages?

232. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET AND AFFILIATED UTE PRESUMPTIONS

233. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(j) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(k) The omissions and misrepresentations were material;

(l) Lexicon's securities traded in efficient markets;

(m) Lexicon's shares were liquid and traded with moderate to heavy volume during the Class Period;

(n) Lexicon traded on the NASDAQ and was covered by multiple analysts;

(o) The misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of the Lexicon's securities; and

(p) Plaintiffs and members of the class purchased, acquired and/or sold Lexicon's securities between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

234. At all relevant times, the markets for the Company's securities were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiffs and the Class relied on the price of the Company's securities, which reflected all information in the market, including the misstatements by Defendants.

235. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

236. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

CAUSES OF ACTION

COUNT I
Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

237. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

238. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

239. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Lexicon securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Lexicon securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

240. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Lexicon securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about sotagliflozin.

241. By virtue of their positions at Lexicon, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

242. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Lexicon, the Individual Defendants had knowledge of the details of Lexicon's internal affairs.

243. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of

Lexicon. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Lexicon's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Lexicon securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Lexicon's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Lexicon securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

244. During the Class Period, Lexicon securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Lexicon securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Lexicon securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Lexicon securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

245. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

246. Plaintiffs and members of the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Lexicon's securities. Plaintiffs and the Class would not have purchased the Company's securities at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon disclosure of Defendants' wrongful conduct.

COUNT II
Violation of Section 20(a) of the Exchange Act
(Against the Individual Defendants)

247. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

248. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the truth about sotagliflozin. The Individual Defendants also knew that the Company's failure to disclose these facts made its statements during the Class Period about sotagliflozin false and misleading.

249. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Lexicon, and to correct promptly any public statements issued by Lexicon which had become materially false or misleading.

250. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Lexicon disseminated in the marketplace during the Class Period concerning sotagliflozin. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Lexicon to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Lexicon within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Lexicon securities.

251. Each of the Individual Defendants, therefore, acted as a controlling person of Lexicon. By reason of their senior management positions and/or being directors of Lexicon, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Lexicon to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Lexicon and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

252. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Lexicon.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 30, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing was served on all counsel of record on this 30th day of July, 2019 through the CM/ECF system.

/s/ Willie C. Briscoe
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